(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

CORRECTED VERSION

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
6 September 2002 (06.09.2002)

PCT

(10) International Publication Number
WO 02/067795 A1

(51) International Patent Classification[7]: A61B 17/80

(21) International Application Number: PCT/US02/05310

(22) International Filing Date: 19 February 2002 (19.02.2002)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/270,620 23 February 2001 (23.02.2001) US

(71) Applicant *(for CA only)*: **SYNTHES (U.S.A.)** [US/US]; 1690 Russell Road, Paoli, PA 19301-1222 (US).

(71) Applicant *(for AT, BE, BR, CH, CO, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, JP, LU, MC, MX, NL, NO, PT, SE, TR only)*: **SYNTHES AG CHUR** [CH/CH]; Grabenstrasse 15, CH-7002 Chur (CH).

(72) Inventor: **HEARN, James, P.**; 25 North Avon Drive, Claymont, DE 19703 (US).

(74) Agents: **POISSANT, Brian, M.** et al.; Pennie & Edmonds, LLP, 1155 Avenue of the Americas, New York, NY 10036 (US).

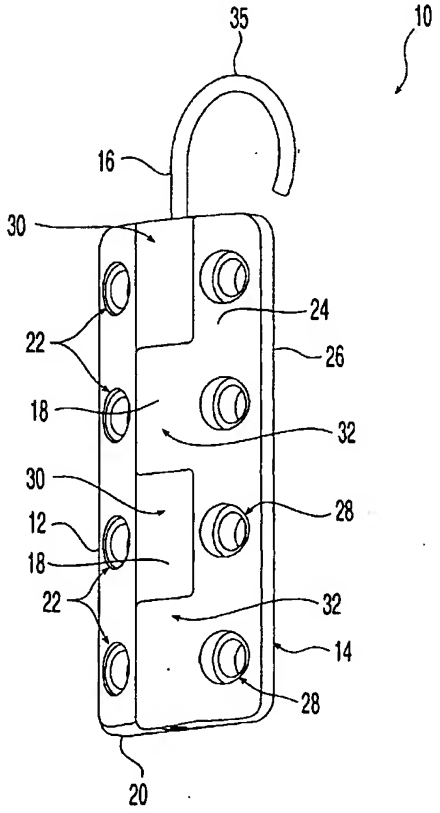
(81) Designated States *(national)*: BR, CA, CO, JP, MX, NO.

(84) Designated States *(regional)*: European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR).

Published:
— *with international search report*

[Continued on next page]

(54) Title: STERNUM FIXATION DEVICE



(57) Abstract: A sternum fixation device for securing parts of a sternum includes first and second removably associated plates. The first plate has an upper surface and a sternum-contacting surface, and at least one hole passing through both of these surfaces for receiving a fastener head. The second plate has at least one attachment member for fixation to teh sternum. A release member holds the first and second plates together, and is movably associated with at least one of the first and second plates such that is may be moved to allow separation of the two parts of the sternum.

WO 02/067795 A1

(48) **Date of publication of this corrected version:**
25 September 2003

(15) **Information about Correction:**
see PCT Gazette No. 39/2003 of 25 September 2003, Section II

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
8 April 2004 (08.04.2004)

PCT

(10) International Publication Number
WO 2004/028412 A1

(51) International Patent Classification[7]: A61F 2/30

(21) International Application Number:
PCT/KR2003/001926

(22) International Filing Date:
23 September 2003 (23.09.2003)

(25) Filing Language: Korean

(26) Publication Language: English

(30) Priority Data:
10-2002-0059059
28 September 2002 (28.09.2002) KR

(71) Applicant *(for all designated States except US)*: **MEDIX-ALIGN CO., LTD.** [KR/KR]; 1205 Aju Building, 679-5 Yeoksam-dong, Gangnam-gu, Seoul 135-916 (KR).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **KIM, Kyung-Tae** [KR/KR]; 104-1504 Samsung APT., 25/8, 593 Junggye-dong, Nowon-gu, Seoul 139-220 (KR). **KIM, Jung-Sung** [KR/KR]; 101-303 Hakyeoul Cheonggu APT., 354 Hagye-dong, Nowon-gu, Seoul 139-230 (KR). **KIM, Byung-Soo** [KR/KR]; 1 Junggokvilla, 104-91 Junggok 4-dong, Gwangjin-gu, Seoul 143-224 (KR). **SHIN, Tae-Jin** [KR/KR]; 303 Deogu Building, 85-38 Dongseon-dong 1-ga, Seongbuk-gu, Seoul 136-051 (KR). **CHOI, Young-Ho** [KR/KR]; 1403-1402 Hugokmaeul, 1101 Ilsan-dong, Ilsan-gu, Goyang-si, Gyeonggi-do 411-310 (KR).

(74) Agent: **HAN YANG PATENT FIRM**; 10th Floor, Dacom Building, 706-1 Yeoksam-Dong, Gangnam-Gu, Seoul 135-987 (KR).

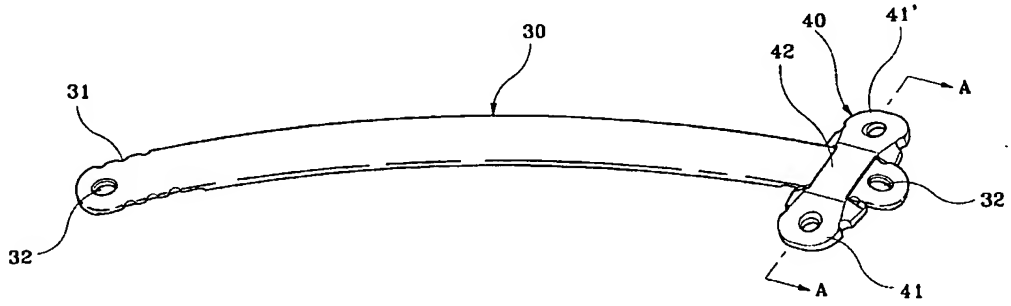
(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: IMPLANT FOR CORRECTION OF PECTUS EXCAVATUM



(57) Abstract: An implant for correcting pectus excavatum is disclosed, which comprises a chest correction bar (30) inserted into a body for lifting a depressed sternum and costal cartilages, and a stabilizer (40) for being inserted into a distal end of the chest correction bar (30) to prevent the chest correction bar from being rotated inside the body, wherein the chest correction bar (30) is formed at both jagged distal ends thereof with recesses (33) each of a predetermined length along the lengthwise direction of the chest correction bar (30), and wherein the stabilizer (40) comprises: two fixing plates (41, 41') for being fixed to the body of a patient; a bridge (42) connecting the two fixing plates (41, 41'); two protruders (43, 43') each generally opposed from the fixing plates (41, 41') so as to be hitched by the recesses (33) at the distal ends of the chest correction bar (30) inserted from under the bridge (42), where there are formed two spaces (C) each of a predetermined size between the two protuders (43, 43') and two lateral lengthwise surfaces of the bridge (42) so that the distal ends of the chest correction bar (30) can be inserted thereinto, thereby allowing the stabilizer (40) to be easily inserted into the chest correction bar (30), and once the insertion is made, pain and infection caused by stimulation on incised portions of a patient can be prevented.

WO 2004/028412 A1

IMPLANT FOR CORRECTION OF PECTUS EXCAVATUM

FIELD OF THE INVENTION

The present invention relates to an implant inserted into a body for correcting pectus excavatum.

BACKGROUND OF THE INVENTION

In general, chest deformity is a case where a chest is more depressed or bulged than that of a normal person due to a depression or elevation of a sternum and surrounding costal cartilages. A depressed chest (pectus excavatum), also known as funnel chest, is particularly the most common anterior chest wall deformity for Asian people. The disfiguring physical appearance of this deformity can cause emotional and social impact especially among children, and may give rise to deterioration in growth or function of organs positioned near the chest area, such that doctors recommend that the depressed chest be operated in childhood.

One conventional surgical procedure for correcting pectus excavatum is to cut out a predetermined portion of inner costal cartilages positioned at both sides of a chest to form grooves therein. Sternum and costal cartilages are pulled forward about the grooves to form a proper thorax, and portions of the grooves at the costal cartilages are artificially filled in to correct the pectus excavatum.

However, there are many disadvantages in the conventional surgical procedure thus described in that the costal cartilages should be carved out from inside the chest, the sternum should be lifted and portions of the grooves must be filled in, thereby prolonging and complicating the operation procedure. It is also causes undue stress for both a surgeon and a patient who has to have his or her costal cartilages removed.

A surgical implant for performing the pectus excavatum procedure which does

not suffer from the above-mentioned disadvantages is needed. One of these implants is disclosed in Korean Utility Model Registration No. 200581, which is hereby incorporated by reference, where an implant for lifting depressed sternum and costal cartilages is embedded into a body and fixed therein, thereby reducing the complexity of the surgical procedure, alleviating a patient's agony, and improving the cosmetic appearance of a person's chest.

The implant disclosed in the Korean Utility Model registration No. 200581 comprises a chest correction bar 10 for lifting the sternum and surrounding costal cartilages in the body, and a stabilizer 20 for being inserted into a distal end of the chest correction bar 10, as illustrated in Fig. 1. The chest correction bar 10 is formed at both distal ends thereof with a plurality of grooves 11 for hitching thread when the thread is sewn for fixing the chest correction bar 10 to a patient's body. The chest correction bar 10 is also formed at the furthest-most end thereof with a hole 12 for tying up the thread when the chest correction bar 10 is inserted into a body.

The stabilizer 20 is formed thereunder with an insertion piece 21 for inserting both ends of the chest correction bar 10 and is also formed with a fixation piece 22 of a predetermined length positioned at a right angle with the chest correction bar 10.

An operational procedure utilizing the conventional implant thus described is also disclosed in the Korean Utility Model registration No. 200581.

In particular, after a surgical tool fixed with a thread has penetrated the patient's chest from side to side, the thread is held by another tool while the surgical tool is pulled out after the implant has been imbedded, leaving the thread remaining in the chest. The thread is tied at the hole 12 formed at the furthest-most end of the chest correction bar 10. The thread is then pulled to allow the chest correction bar 10 to be fixed inside the body. When the chest correction bar 10 is inserted, a concave side thereof with a predetermined curvature should be in contact with the chest. Next,

when both ends of the chest correction bar 10 are held and turned 180 degrees, the chest and costal cartilages are instantly lifted in accordance to the curved shape of the chest correction bar 10, forming the contour of the chest as desired. The chest correction bar 10 thus lifted is fixed using the grooves 11 at both ends thereof by being tied at the skin or muscle, and the stabilizer 20 is inserted into both ends of the chest correction bar 10 to prevent the chest correction bar 10 from being rotated.

There is a disadvantage in the implant for correcting pectus excavatum thus described according to the prior art in that, because a planar surface of the fixation piece 22 at the stabilizer 20 is protrusively formed with the insertion piece 21, the overall thickness of the stabilizer 20 becomes larger, such that when the chest correction bar 10 is inserted, soft tissue around the operated portion are stimulated, causing pain to a patient, and in worst cases, soft tissue may become infected.

Still worse, it is difficult to insert the stabilizer 20 to the body-fitted chest correction bar 10 through a small incised portion because the fixation piece 22 should be inserted in the parallel state with a planar surface of the chest correction bar 10 when the stabilizer 20 is inserted into the chest correction bar 10.

SUMMARY OF THE INVENTION

The present invention provides an implant for correction of pectus excavatum in which a stabilizer is easily inserted into a chest correction bar. Once the stabilizer is inserted, pain and infection caused by stimulation to incised portions of a patient can be prevented.

The implant for correction of pectus excavatum according to the present invention comprises a chest correction bar going through a body for lifting a depressed sternum and costal cartilages, and a stabilizer for being inserted into a distal end of the chest correction bar to prevent the chest correction bar from being rotated inside the

body, wherein the chest correction bar is formed at both jagged distal ends thereof with recesses each of a predetermined length along the lengthwise direction of the chest correction bar. The stabilizer comprises two fixing plates for being fixed to a body of a patient, a bridge connecting the two fixing plates, and two protruders each generally opposed from the fixing plates so as to be hitched by the recesses at the distal ends of the chest correction bar inserted from under the bridge, where, between the two protruders and two lateral lengthwise surfaces of the bridge, there are formed two spaces each of a predetermined size so that the distal ends of the chest correction bar can be inserted thereinto.

Preferably, the protruders are pins attached to the fixing plates.

The fixing plates are formed at lateral surfaces thereof with grooves at which threads can be hitched when the threads are tied for securing the stabilizer to the body of a patient.

Preferably, the fixing plates are centrally formed with through holes for reducing the weight of the stabilizer and for hitching threads as well in case of need.

Preferably, the central planar portion of the chest correction bar is cut out lengthwise such that the thickness of the central portion of the chest correction bar is thinner than that of the distal ends thereof.

BRIEF DESCRIPTION OF THE DRAWINGS

For fuller understanding of the nature and objects of the present invention, reference should be made to the following detailed description taken in conjunction with the accompanying drawings in which:

Fig. 1 is an exploded perspective view of an implant for correcting pectus excavatum according to the prior art;

Fig. 2 is a coupled perspective view of an implant for correcting pectus excavatum according to the first embodiment of the present invention;

Fig. 3 is a partial cross-sectional view taken along A-A of Fig. 2, where only cross-sections of both sides of the stabilizer and cross-section of the chest correction bar are shown;

Figs. 4a and 4b are perspective views of the chest correction bar and the stabilizer for implant according to the first embodiment of the present invention;

Fig. 5 is plan view of the stabilizer of Fig. 4b;

Figs. 6-8 are constitutional views where a stabilizer is inserted into distal ends of a chest correction bar for implant according to the first embodiment of the present invention;

Fig. 9 is a perspective view of a stabilizer for implant according to a second embodiment of the present invention; and

Fig. 10 is a perspective view of a chest correction bar for implant according to a third embodiment of the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The preferred embodiments of the present invention will now be described in detail with reference to the accompanying drawings.

Fig. 2 is a coupled perspective view of an implant for correcting pectus excavatum according to the first embodiment of the present invention and Fig. 3 is a partial cross-sectional view taken along A-A of Fig. 2.

As depicted in the drawings, the implant according to the present invention comprises a chest correction bar 30 going through a body for lifting a depressed sternum and surrounding costal cartilages, and a stabilizer 40 for being inserted into a distal end of the chest correction bar 30 to prevent the chest correction bar 30 from being rotated inside the body.

The chest correction bar 30 and the stabilizer 40 are made of unharmful and

rust-proof biocompatible metals such as stainless steel, titanium alloy, cobalt-chrome alloy and the like, and also may be made of biocompatible polymer or copolymer such as Utra High Molecular Weight Polythylene (UHMWPE), Poly L-Lactide Acid (PLLA), Poly Glycolic Acid (PGA), Poly D-Lactide Acid (PDLA).

As shown in Figs. 2, 4a and 4b, the chest correction bar 30 features a curved strip-type elongated bar having a predetermined curvature to smoothly connect costal cartilages at both sides of a body and to lift the sternum and the costal cartilages, and has a bending strength and stiffness so that the curvature of the chest correction bar 30 can be appropriately adjusted in relation to the chest width and chest contour of a patient.

The chest correction bar 30 has a planar surface. Although it is preferred that the bar 30 is bent for use by a patient according to his or her chest contour, it is also possible that the bar 30 is manufactured with a predetermined contour. In the first embodiment of the present invention, the bar 30 is bent with an arbitrary contour.

The chest correction bar 30 is formed at both marginal end surfaces thereof with a plurality of grooves 31 so as to be hitched when threads are tied for securing the bar 30 to the body of a patient.

The chest correction bar 30 is also formed at both furthestmost distal ends thereof with through holes 32 for holding threads when the bar 30 is inserted into a body. Furthermore, inwardly bent sides of both distal ends of the chest correction bar 30 are lengthwise formed with recesses 33 each of a predetermined length.

The stabilizer 40 comprises: two fixing plates 41 and 41' for being fixed to the body of a patient; a bridge 42 connecting the two fixing plates 41 and 41'; two protruders 43 and 43' each generally opposed from the fixing plates so as to be hitched by the recesses 33 at the distal ends of the chest correction bar 30 inserted from under the bridge 42, where, between the two protruders 43 and 43' and two lateral lengthwise surfaces of the bridge 42, there are formed two spaces (C) each of a predetermined size so that the distal ends of the chest correction bar 30 can be inserted thereinto (refer to

Fig. 5).

The fixing plates 41 and 41' are formed at lateral surfaces thereof with lateral grooves 41a and 41'a for holding thread when the thread is tied for securing the stabilizer 40. The fixing plates 41 and 41' are centrally formed with through holes 41b and 41'b for reducing the weight of the stabilizer 40 and for holding the thread in case of need.

The operating method of using the above-identified implant thus described according to the present invention in which the implant is inserted into the body of a patient and tied by thread is the same as that of the prior art.

Furthermore, distal ends of the chest correction bar 30 inserted into the body of a patient and protruding out of the body at both ends thereof are fitted by a stabilizer. As illustrated in Fig. 6, the planar surface of the stabilizer 40 is disposed at a right angle by planar surface of the chest correction bar 30, which in turn is inserted into the spaces depicted as C (refer to Fig. 5) formed by the protruders 43, 43' and widthwise lateral surfaces of the bridge 42 of the stabilizer 40 as shown in Fig. 7. Then the stabilizer 40 is rotated as seen in Fig. 8 to allow both planar surfaces of the stabilizer 40 and the chest correction bar 30 to be in parallel, and the stabilizer 40 is insertedly coupled in the lengthwise direction of the chest correction bar 30. As a result, the stabilizer 40 can be easily inserted into the chest correction bar 30 that is closely contacting the body.

Fig. 9 is a perspective view of a stabilizer of an implant according to a second embodiment of the present invention.

The stabilizer 40 according to the teachings of the second preferred embodiment of the present invention is mounted with the protruders of the first embodiment in the form of pins 143 and 143' attached to fixing plates 141 and 141'.

The bridge 142, lateral grooves 141a and 141'a and through holes 141b and 141'b are the same as those of the first embodiment.

Fig. 10 is a perspective view of a chest correction bar of an implant according to a third embodiment of the present invention.

An intermediate thickness assigned to a chest correction bar 230 according to the teachings of the third preferred embodiment of the present invention is thinner than distal ends of the chest correction bar such that a central portion of the chest correction bar 230 in between the two distal ends thereof is hollowed. Construction of lateral grooves 231, through holes 232 and recesses 233 are the same as that of the first embodiment of the present invention.

The chest correction bar 230 of the teachings of the third embodiment of the present invention therefore may be reduced in weight due to the hollowed central portion thereof to be stably coupled with a stabilizer.

The foregoing discussion has disclosed and described merely exemplary embodiments of the present invention. It is not intended to be exhaustive or to limit the invention to the precise form disclosed, and modifications and variations are possible in light of the above teachings or may be acquired from practice of the invention.

As apparent from the foregoing, there is an advantage in the implant for correcting pectus excavatum thus described according to the present invention in that it is easy to insert a stabilizer to a chest correction bar due to the thinness of the stabilizer, and once the stabilizer is inserted, pain and infection caused by stimulation to incised parts of a patient can be prevented.

There is another advantage in that, when the stabilizer is inserted to the chest correction bar, the planar surface of the stabilizer is initially inserted at right angle into

the planar surface of the chest correction bar but later rotated to place itself in parallel position with the planar surface of the chest correction bar, making it easy to insert the stabilizer.

WHAT IS CLAIMED IS:

1. An implant for correcting pectus excavatum, comprising:

a chest correction bar for lifting a depressed sternum and costal cartilages; and

a stabilizer for being inserted into a distal end of said chest correction bar to prevent said chest correction bar from being rotated inside the body,

wherein said chest correction bar is formed at both distal ends thereof with recesses along the lengthwise direction of said chest correction bar, and wherein said stabilizer comprises: two fixing plates for being fixed to the body of a patient; a bridge connecting the two fixing plates; two protruders each opposed from the fixing plates so as to be hitched by said recesses of said chest correction bar inserted from under the bridge, where there are formed two spaces between said two protruders and said two lateral widthwise surfaces of the bridge, each space being of a predetermined size so that the distal ends of said chest correction bar can be inserted thereinto.

2. The implant as defined in claim 1, wherein said protruders are composed of pins attached to the fixing plates.

3. The implant as defined in claim 1, wherein said fixing plates are formed at lateral surfaces thereof with grooves for hitching thread when the thread is tied for securing said stabilizer to the body of a patient.

4. The implant as defined in claim 1, wherein said fixing plates are centrally formed with through holes for reducing the weight of said stabilizer and for hitching thread in case of need.

5. The implant as defined in claim 1, wherein the central planar portion of said chest correction bar is cut out lengthwise such that thickness of the central portion of said chest correction bar is thinner than that of the distal ends thereof.

FIG.1

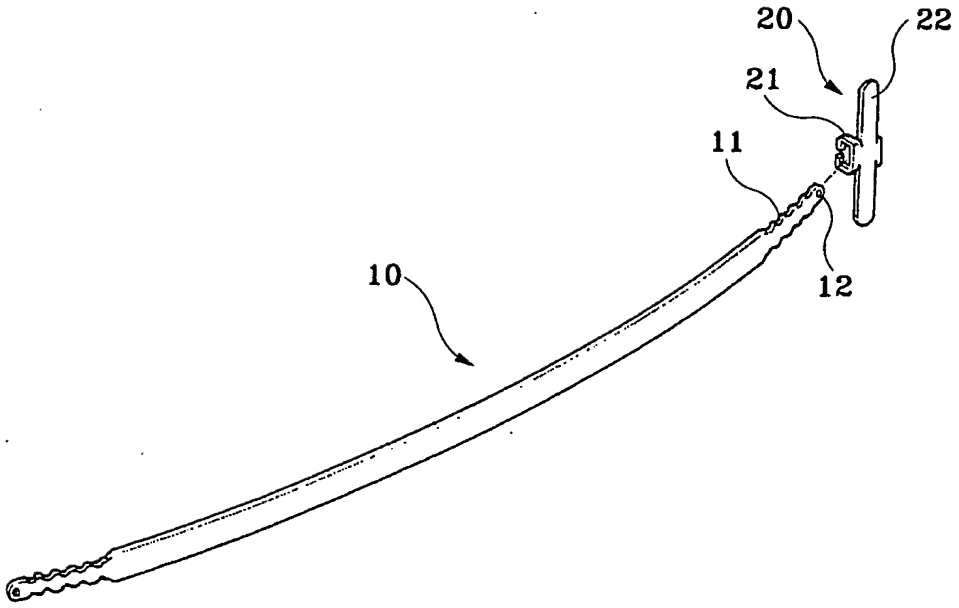


FIG.2

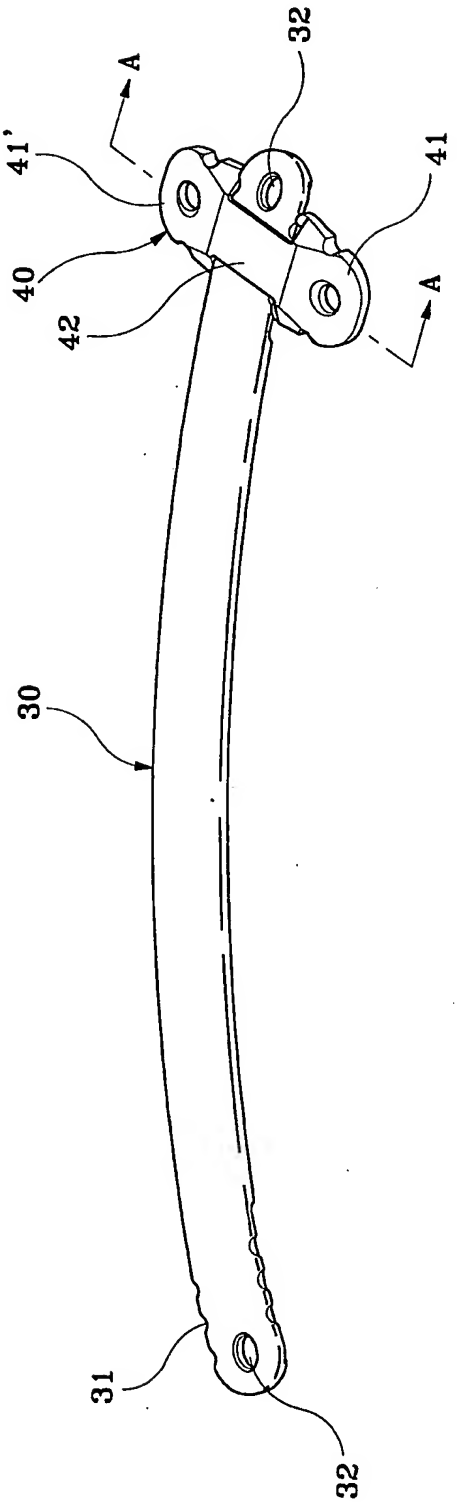


FIG.3

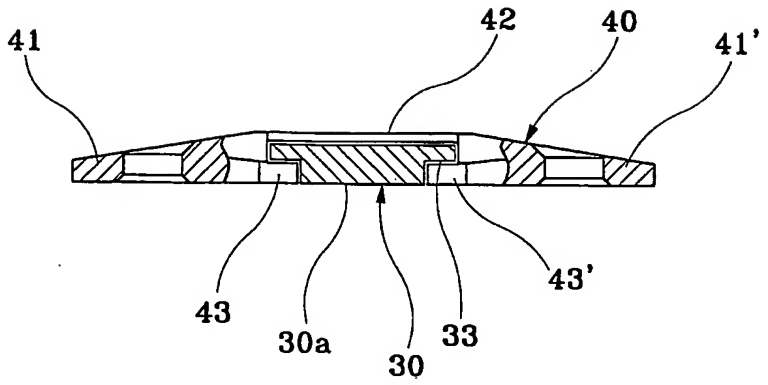


FIG.4a

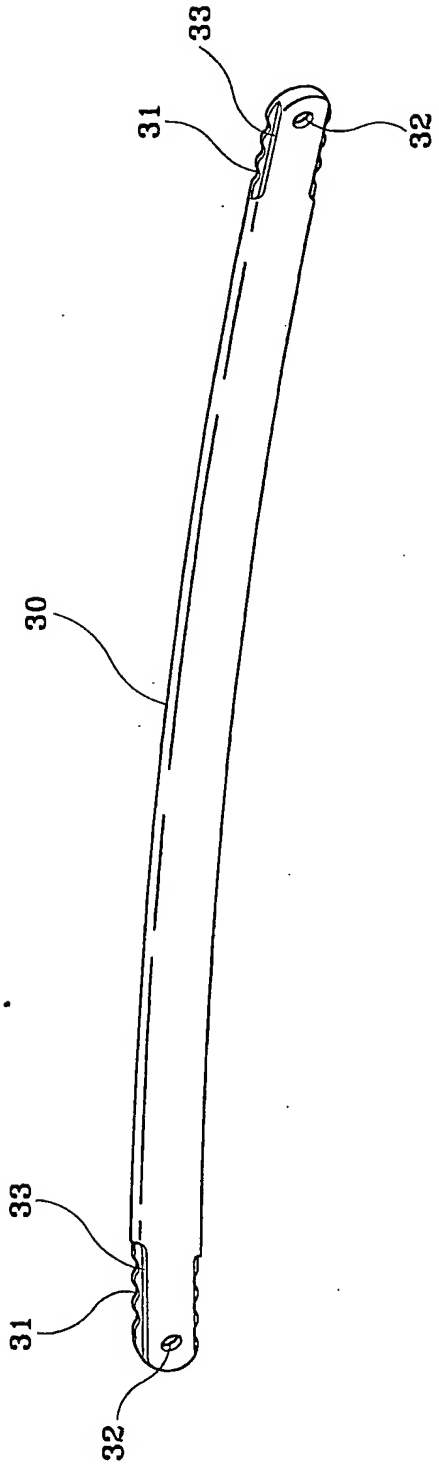


FIG.4b

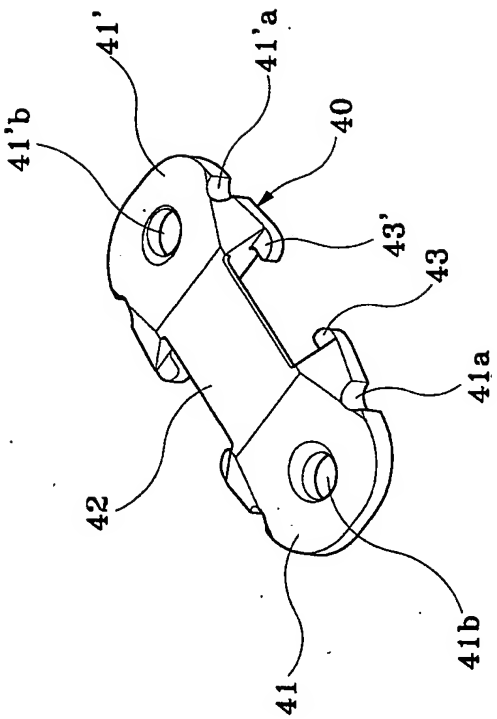


FIG.5

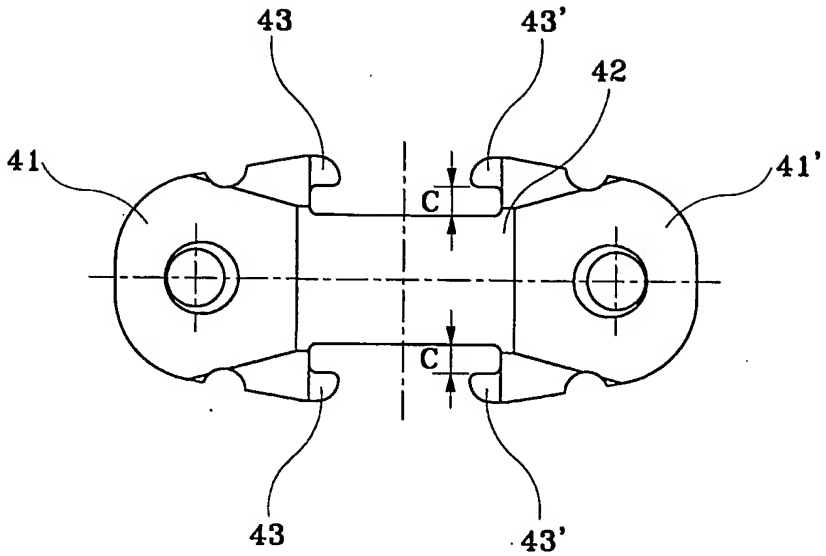


FIG.6

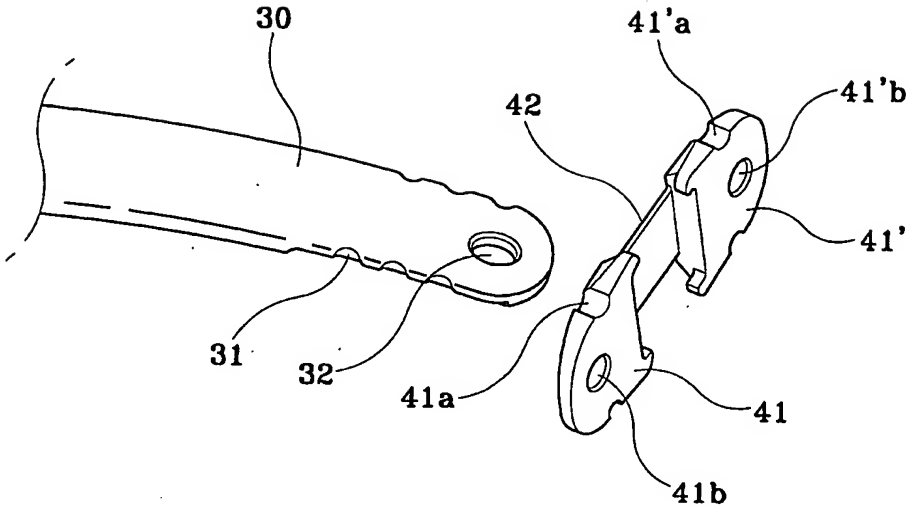


FIG.7

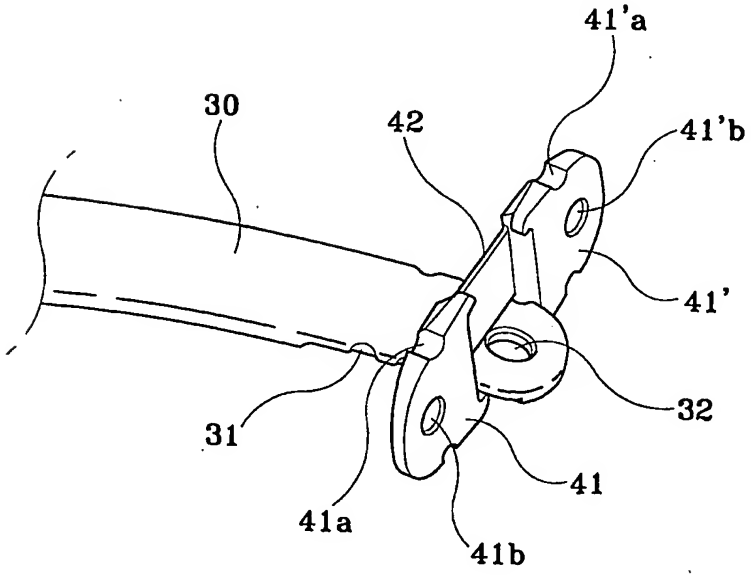


FIG.8

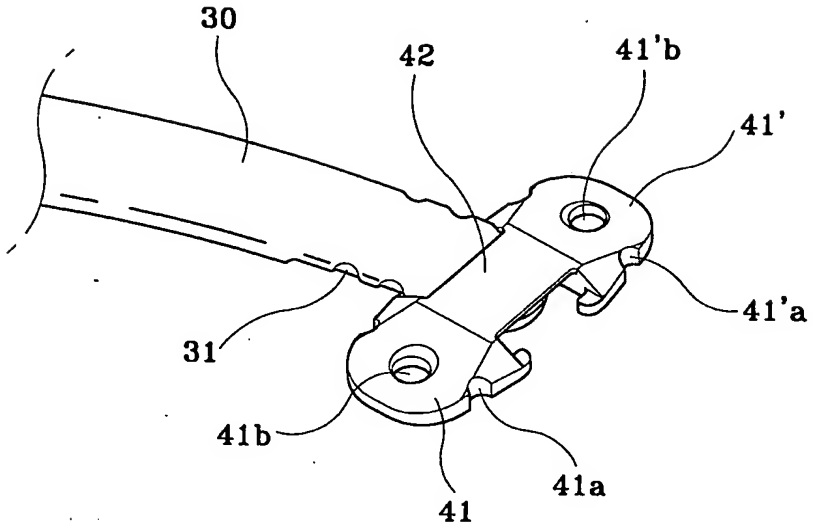

30
42
41'b
41'
41'a
31
41b
41
41a

FIG.9

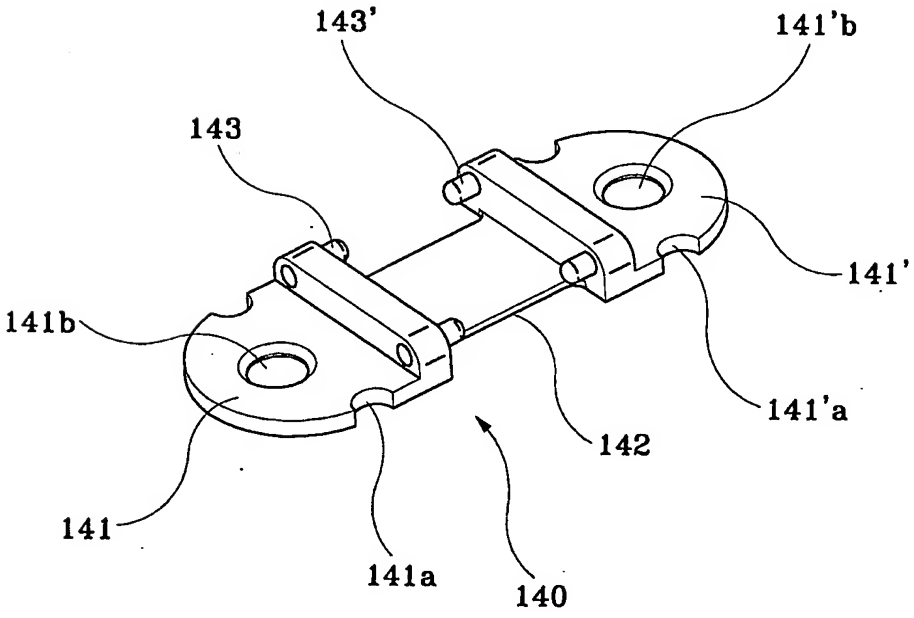
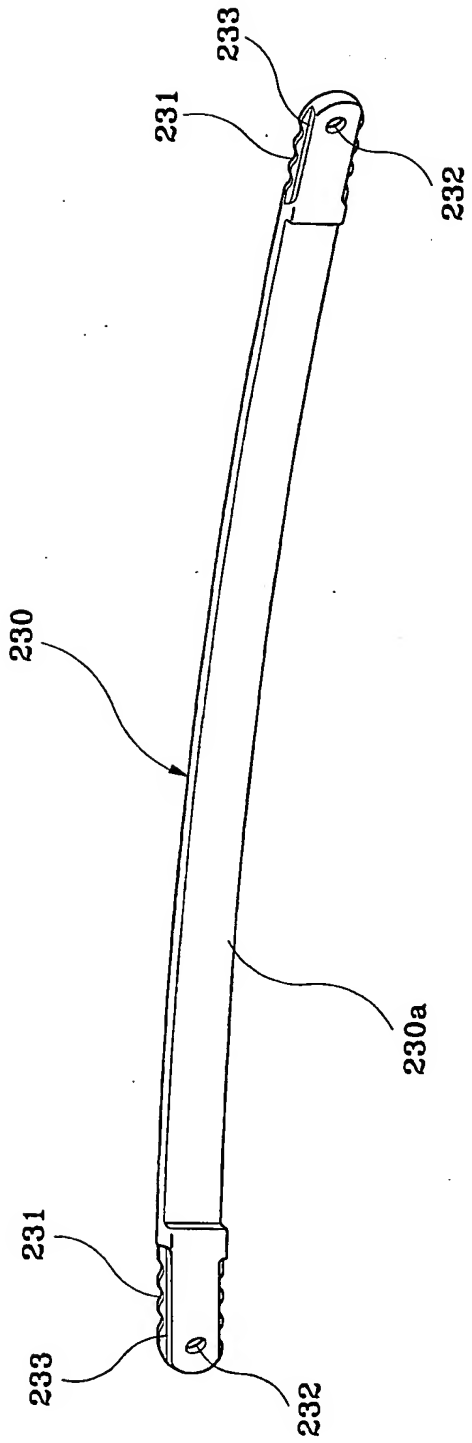

143'
141'b
143
141'
141b
141'a
142
141
141a
140

FIG.10



INTERNATIONAL SEARCH REPORT

International application No.
PCT/KR03/01926

A. CLASSIFICATION OF SUBJECT MATTER

IPC7 A61F 2/30

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
Korean Patents and Applications for Inventions; Korean Utility Models and Applications for Utility Models since 1975
Japanese Utility Models and Applications for Utility Models since 1975

Electronic data base consulted during the internationl search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	KR 20-0200581 Y1 (JONG YOON-SEB) 10. 08. 2000. See the whole document: especially claims and figures	1~5
Y	US 6,024,759 A (Walter Lorenz Surgical, Inc.) 15. 02. 2000. See the whole document: especially claims and figures	1~5
A	JP 08-280723 A (Waldemar Link Gmbh & Co.) 29. 10. 1996. See the abstract and figures	1~5

☐ Further documents are listed in the continuation of Box C.

☐ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents,such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
29 DECEMBER 2003 (29.12.2003)	30 DECEMBER 2003 (30.12.2003)

Name and mailing address of the ISA/KR
Korean Intellectual Property Office
920 Dunsan-dong, Seo-gu, Daejeon 302-701,
Republic of Korea
Facsimile No. 82-42-472-7140

Authorized officer
KOH, Tae Wook
Telephone No. 82-42-481-5574

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
6 September 2002 (06.09.2002)

PCT

(10) International Publication Number
WO 02/067795 A1

(51) International Patent Classification[7]: A61B 17/80

(21) International Application Number: PCT/US02/05310

(22) International Filing Date: 19 February 2002 (19.02.2002)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/270,620 23 February 2001 (23.02.2001) US

(71) Applicant *(for CA only)*: **SYNTHES (U.S.A.)** [US/US]; 1690 Russell Road, Paoli, PA 19301-1222 (US).

(71) Applicant *(for AT, BE, BR, CH, CO, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, JP, LU, MC, MX, NL, NO, PT, SE, TR only)*: **SYNTHES AG CHUR** [CH/CH]; Grabenstrasse 8, CH-7002 Chur (CH).

(72) Inventor: **HEARN, James, P.**; 25 North Avon Drive, Claymont, DE 19703 (US).

(74) Agents: **POISSANT, Brian, M.** et al.; Pennie & Edmonds, LLP, 1155 Avenue of the Americas, New York, NY 10036 (US).

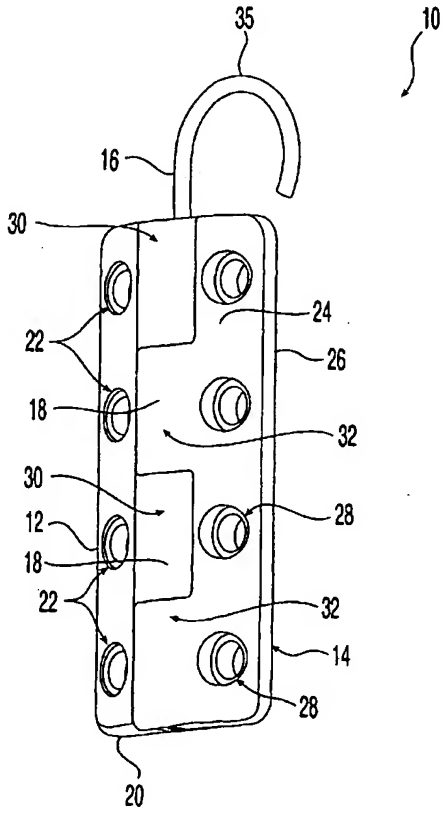
(81) Designated States *(national)*: BR, CA, CO, JP, MX, NO.

(84) Designated States *(regional)*: European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR).

Published:
— *with international search report*

[Continued on next page]

(54) Title: STERNUM FIXATION DEVICE



(57) Abstract: A sternum fixation device for securing parts of a sternum includes first and second removably associated plates. The first plate has an upper surface and a sternum-contacting surface, and at least one hole passing through both of these surfaces for receiving a fastener head. The second plate has at least one attachment member for fixation to teh sternum. A release member holds the first and second plates together, and is movably associated with at least one of the first and second plates such that is may be moved to allow separation of the two parts of the sternum.

WO 02/067795 A1

— *.before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

STERNUM FIXATION DEVICE

FIELD OF THE INVENTION

The present invention relates generally to surgical devices, and more particularly, to devices for reapproximating two or more parts of a patient's sternum.

BACKGROUND OF THE INVENTION

Many surgical procedures require two or more parts of a sternum to be reapproximated, or fixed together, such as sternal reconstruction and repair of sternal trauma. In addition, various types of surgical procedures are currently performed to investigate, diagnose, and treat diseases involving tissues or organs located in a patient's thoracic cavity, such as the heart and lungs. These procedures typically require a partial or median sternotomy to gain access to the patient's thoracic cavity. A partial or median sternotomy is a procedure by which a saw or other appropriate cutting instrument is used to make a midline, longitudinal incision along a portion or the entire axial length of the patient's sternum, allowing two opposing sternal halves to be separated laterally. A large opening into the thoracic cavity is thus created, through which a surgeon may directly visualize and operate upon the heart and other thoracic organs, vessels, or tissues. Following the surgical procedure within the thoracic cavity, the two severed sternal halves must be reapproximated.

Sternum fixation has traditionally has been performed using stainless steel wires that are wrapped around or through the sternal halves and then twisted together, so as to compress the two halves together. Other methods of sternum fixation include the use of band or strap assemblies. Such assemblies typically include a locking mechanism, which secures a strap in a closed looped configuration around the sternum halves. While utilization of steel wires and strap assemblies have been widely accepted for sternum fixation, these devices present a number of disadvantages. For example, steel wires are susceptible to breakage, are difficult to maneuver and place around the sternum, and often have sharp ends that can pierce through the surgeon's gloves or fingers. Steel wire and band assemblies also provide insufficient or non-uniform clamping force on the sternal halves, thus resulting in sternal nonunion. The steel wire and band assemblies also provide insufficient clamping forces in all three planar directions, thus leading to healing problems caused by unwanted bone movements leading to raking and rubbing of the surrounding tissue or bone.

Several other techniques of sternal fixation have been developed for

reapproximating the sternal halves. One technique uses plates that are located on both sternal halves across the sternotomy and are fixed thereto by means of screws through the bone on either side of the sternotomy. This technique, however, is not optimal because it requires direct fixation of the plates to the bone with screws, making reentry into the thoracic cavity through the sternotomy extremely difficult in case of a medical emergency.

Another technique uses a sternal clamp having a pair of opposed generally J-shaped clamp members which are laterally adjustable relative to one another but can be rigidly joined with a set of machine screws. Similar to the use of plates, discussed above, this technique does not provide quick access to the organs and/or tissues within the patient's thoracic cavity.

Yet another fixation device comprises a pair of hook-shaped clamps that slide together and lock in position with respect to one another using a ratchet assembly. The ratchet assembly provides quickened accesses to the thoracic cavity, but is cumbersome to use and is limited to the hook-shaped clamp members disclosed.

Therefore, it is desirable to provide a sternum fixation device that stabilizes the sternum in all three planar directions, has a fast and easy to use quick-release feature, and works in several different configurations.

SUMMARY OF THE INVENTION

The present invention is directed to a sternum fixation device for securing parts of a sternum. The sternum fixation device includes a first plate and a second plate. The first plate has an upper surface and a sternum-contacting surface, at least one hole passing through the upper and sternum-contacting surfaces for receiving a fastener head of a bone fastener, and a first longitudinal bore defining an axis oriented substantially transversely to the at least one hole. The at least one hole may be threaded to receive a threaded fastener head. The second plate has an upper surface and a sternum-contacting surface, an attachment member for fixation to the sternum, and a second longitudinal bore. The first and second plates are dimensioned to mate with one another such that the first and second longitudinal bores are aligned to receive the release member, and removal of the release member from the first and second longitudinal bores allows separation of the two parts of the sternum. The first and second plates mate with one another such that they cannot rotate with respect to one another about the release member.

According to one aspect of the present invention, the release member is a pin, which may be a single pronged pin. The pin may have a splayed apart tip portion. Alternatively, the release member is a two pronged pin, which may be angled with respect

to a mating line between the first and second plates. The release member may also be a cam or quarter-turn fastener, and the first and second plates may be provided with matching sets of ratchet teeth that cooperate with the release member to allow the distance between the first and second plates to be varied.

The attachment member may be a threaded through hole that passes through the second plate upper and sternum-contacting surfaces for receiving a threaded fastener head. To increase pull-out resistance of the fastener, the at least one threaded hole may be angled away from the second plate.

According to another embodiment of the present invention, the attachment member is a hook member for engaging an intercostal space portion of the sternum. Preferably, the attachment member comprises at least two hook members that are spaced apart by an adjustable lateral distance. Alternate embodiments include multiple combinations of fastener and hook-shaped attachment members.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of a first embodiment of a sternum fixation device according to the present invention;

FIG. 2 is an exploded perspective view of the sternum fixation device of FIG. 1;

FIG. 3 is a perspective view of the sternum fixation device of FIG. 1, having a U-shaped release member;

FIG. 4 is an exploded perspective view of the sternum fixation device of FIG. 3;

FIG. 5 is a perspective view of the sternum fixation device of FIG. 1, having differently shaped first and second mating portions;

FIG. 6-7 are exploded perspective views of the sternum fixation device of FIG. 5, showing variations of the first and second mating portions and release member;

FIG. 8 is an elevational view of the sternum fixation device of FIG. 5, wherein the release member is angled with respect to a mating line between the first and second plates;

FIG. 9 is a perspective view of the sternum fixation device of FIG. 1, having differently shaped first and second mating portions;

FIG. 10-12 are elevational views of the sternum fixation device of FIG. 5, having additional first and second attachment members;

FIG. 13 is a perspective view of the sternum fixation device of FIG. 5, having additional first and second attachment members;

FIG. 14 is a perspective view of a sternum fixation device of FIG. 1, having an alternate embodiment of the release member of FIG. 1;

FIG. 15 is a perspective view of a second embodiment of a sternum fixation device according to the present invention, having hook-shaped attachment members;

FIG. 16 is a perspective view of the sternum fixation device of FIG. 15, having adjustably spaced-apart hook members;

FIG. 17 is a perspective view of the sternum fixation device of FIG. 15, having first and second attachment members including a combination of hooks and threaded fastener holes;

FIG. 18 is a perspective view of the sternum fixation device of FIG. 15, having an alternate embodiment of the release member; and

FIG. 19 is an elevational view of a bone fastener having a threaded head portion for use with one embodiment of the first and second attachment members according to the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

FIGS. 1 and 2 show a first illustrative embodiment of a sternum fixation device according to the present invention, shown as sternum fixation device 10. Sternum fixation device 10 includes first and second mating plates 12, 14 attached to one another by a release member 16. First plate 12 and second plate 14 may be used to reapproximate, or secure together, two or more parts of a sternum by attaching each plate to a part of the sternum. Sternum fixation device 10 may be constructed from any suitable bio-compatible material including, but not limited to, bioresorbable materials, radio-translucent materials, allograft materials, stainless steel and titanium

First plate 12 includes an upper surface 18 and a sternum-contacting surface 20, and a first attachment member 22 for attachment to the sternum. First attachment member 22 is shown as a plurality of threaded holes that are configured to receive a threaded head portion 44 of a fastener, such as a bone screw 42, shown in FIG. 19. The fastener may alternatively have an elongated shaft with barbs formed thereon that anchor the fastener in the bone. Second plate 14 includes an upper surface 24 and a sternum-contacting surface 26, and a second attachment member 28, also shown as a plurality of threaded holes for receiving a threaded head portion of a bone screw 42. Alternatively, the

holes of the first and second attachment members 22, 28 may not have threads and receive a non-threaded head portion of a fastener. Sternum-contacting surfaces 20, 26 may be scalloped, or provided with various other surface treatments that are known by one of ordinary skill in the bone plating art to minimize the contact area between the first and second plates 12, 14 and the respective parts of the sternum.

First plate 12 further includes a series of first joining portions 30 that inter-digitate with corresponding second joining portions 32 on second plate 14. A first longitudinal bore 34 extends through the first joining portions 30 and a second longitudinal bore 36 extends through the second joining portions 32 such that when first plate 12 and second plate 14 are positioned adjacent one another with the first and second joining portions 30, 32 inter-digitated, the first and second longitudinal bores 34, 36 are substantially aligned and may receive release member 16. Alternatively, the first and second joining portions 30, 32 could be provided with multiple sets of aligned longitudinal bores to allow the distance between the first and second attachment members 22, 28 to be varied to accommodate a range of sternum sizes.

As shown in FIGS. 1 and 2, release member 16 is shown as an elongated pin having a curved grip portion 35. Release member 16 could alternatively have a T-shaped grip portion. When inserted into aligned first and second longitudinal bores 34, 36, release member 16 secures the first and second plates 12, 14 together. As shown in FIG. 2, when the release member 16 is removed from the first and second longitudinal bores 34, 36, the first and second plates 12, 14 are allowed to separate. Thus, release member 16 can be removed from the first and second longitudinal bores 34, 36 to quickly and conveniently gain access to the thoracic cavity. This quick release mechanism can be useful, for example, in the case of a medical emergency.

According to one aspect of the present invention, first and second joining portions 30, 32 may be configured such that the first and second plates 12, 14 cannot rotate with respect to one another about the release member 16, thus providing increased stabilization of the two parts of the sternum. As shown in FIG. 2, the first and second joining portions 30, 32 overlap as well as inter-digitate, thus fixing the plates together such that they do not rotate with respect to one another. As an alternative to overlapping the joining portions, release member 16 may be configured to prevent relative rotation between the first and second plates 12, 14. For example, release member 16 and the first and second longitudinal bores 34, 36 may have matching polygonal cross-sections, such as rectangular, square, or triangular, which prevent rotation of either of the plates 12, 14 relative to the release member 16 and consequently, relative to one another. The matching cross-sections

may also be ovular. Alternatively, release member 16 may be a multi-pronged pin and the first and second joining portions 30, 32 may be provided with multiple sets of aligned longitudinal bores. One of ordinary skill in the bone plating art, however, will know and appreciate than any number of configurations may be used to prevent rotation between the first and second plates 12, 14.

Referring to FIGS. 3 and 4, a variation of sternum fixation device 10 is shown with release member 16 in the form of a U-shaped pin having spaced apart leg portions 37, 39. The first and second plates 12, 14 have first and second joining portions 30, 32 that are spaced apart such that a central opening 33 is defined between the first and second plates 12, 14. Central opening 33 serves to minimize the amount of implanted material that contacts the sternum. A third longitudinal bore 38 extends through the first mating portion 30 and a fourth longitudinal bore 40 extends through the second mating portion 32. The third and forth longitudinal bores 38, 40 are located such that when the first plate 12 and second plate 14 are positioned adjacent one another with the first and second joining portions 30, 32 inter-digitated, the first and second longitudinal bores 34, 36 are substantially aligned, as are the third and forth longitudinal bores 38, 40. Thus, each of the release member leg portions 37, 39 may be received in one of the aligned pairs of bores to secure the first and second plates 12, 14 together. The spaced apart relationship of leg portions 37, 39 and the respective sets of aligned longitudinal bores prevents the first and second plates 12, 14 from rotating with respect to one another about the release member 16, thus stabilizing the sternum fixation device 10.

Still referring to FIGS. 3 and 4, the first and second attachment members 22, 28 are in the form of a plurality of threaded holes configured to receive a threaded head 44 of a bone screw 42. To reduce the tendency of the bone screws 42 to pull out of the sternum, the threaded holes of the first attachment member 22 and the second attachment member 28 may be angled such that the threaded tip portions 46 of opposing bone screws, for example, bone screws 42a and 42b, are angled towards one another.

FIGS. 5-12 show several additional variations of sternum fixation device 10. In each of the variations shown, first and second plates 12, 14 are reduced in size so that they outline the first and second attachment members 22, 28, thereby reducing the amount of material that contacts the sternum. Referring to FIGS. 5, 6 and 7, the first and second joining portions 30, 32 may each have protrusions and/or indentations formed thereon to prevent them from rotating with respect to one another. As shown in FIG. 6, second joining portion 32 includes transverse tabs 48 and groove 50, and first joining portion 30 has mating grooves 52 and tab 54 formed thereon, which cooperate to prevent rotation between the first

and second plates 12, 14. Release member 16 has a resiliently expanded, or splayed, tip portion 56 that provides resistance against the release member 16 coming out of first and second longitudinal bores 34, 36. Release member 16 may alternatively be a taper pin. As shown in FIG. 7, tabs 48 and grooves 52 may be oriented parallel to the joining portions, however, one of ordinary skill in the bone plating art will know and appreciate that any number of configurations of mating protrusions and/or indentations may be formed on the first and second mating portions 30, 32 to prevent rotation between them.

FIG. 8 shows a variation of sternum fixation device 10 wherein the first and second longitudinal bores 34, 36 are oriented at an angle 58 to the intersection 57 of first and second plates 12, 14. When release member 16 is received in aligned first and second longitudinal bores 34, 36 (hidden in FIG. 8), the skewed orientation of release member 16 with respect to intersection 57 prevents rotation between the first and second plates 12, 14. FIG. 9 shows another variation of sternum fixation device 10 having a release member 16 in the form of a U-shaped pin, as discussed above with respect to FIGS. 3 and 4. Release member 16 could alternatively be a V-shaped pin, a T-shaped pin, or any other shape known to one of ordinary skill in the art. FIG. 10 shows a variation of sternum fixation device 10 having first and second attachment members 22, 28 comprising three threaded fastener or screw holes each, and a skewed release member 16. FIG. 11 shows another variation having a U-shaped release member 16 with an enlarged ring-shaped grip portion 35. FIG. 12 shows yet another variation where first attachment member 22 and second attachment member 28 each comprise six threaded fastener or screw holes for receiving a threaded head 44 of a bone fastener or bone screw 42. FIG. 13 shown a variation where the first attachment member 22 and the second attachment member 28 are arranged in a H-shaped pattern. One of ordinary skill in the bone plating art will know and appreciate that any of the features and variations described above may be combined to produce a sternum fixation device according to the present invention.

FIG. 14, shows an alternate embodiment of a release member 116 according to the present invention, which comprises a pair of quarter-turn fasteners or screws, or other cam-type screws known by one of ordinary skill in the art. The first joining portions 130 each have a countersunk bore 134 for receiving a head 135 of the release member 116, and the second joining portions 132 each have a threaded bore, or cam surface 136 (hidden in FIG. 14), for receiving a threaded or cam portion 137 (hidden in FIG. 14) of the release member 116, or vice versa. The first joining portions 130 overlap the second joining portions 132, or vice versa, such that the release member 116 can be inserted through the countersunk bore 134 and be received by cam surface 136 to secure the first and second

plates 12, 14 together. To separate the first and second plates 12, 14 the release member 116 is rotated through a predetermined angle preferably of less than 360 degrees, such as, for example ninety degrees, to release the cam portion 137 of the release member 116 from the cam surface 136 and allow the first and second plates 12, 14 to come apart.

Referring to FIGS. 14-17, a second embodiment of the present invention is shown as sternum fixation device 210. Sternum fixation device 210 includes first and second plates 212, 214 attached to one another by release member 216. First plate 212 includes an upper surface 218 and a sternum-contacting surface 220, and first attachment member 222. As will be discussed in more detail below, first attachment member 222 is a plurality of hooks that are configured and dimensioned to engage the sternum between the intercostal spaces. Second plate 214 includes an upper surface 224 and a sternum-contacting surface 226, and second attachment member 228. Second attachment member 228 is a plurality of holes for receiving a bone fastener or screw 242, which holes are preferably threaded to receive a threaded head 244 of the bone screw 242.

First plate 212 further includes a first joining portion 230 that overlaps with corresponding second joining portion 232 on second plate 214. An elongated slot 234 extends through the second joining portion 232 and is dimensioned to receive release member 216, which is a cam, as shown in FIGS. 14 and 15, or quarter-turn fastener or screw, as shown in FIG. 16. As shown in FIGS. 14 and 15, release member 216 may be a generally rectangular cam that is rotatable between a locking position and a releasing position and has a first dimension 260 that can pass through the slot 234 when it is oriented parallel thereto, but can not pass through the slot 234 when it is substantially transverse thereto. Thus, when release member 216 is in the locking position, the first dimension 260 is oriented substantially transverse to the elongated slot 234 and locks the first and second plates 212, 214 together. When release member 216 is rotated into the releasing position, the first dimension 260 is in alignment with the elongated slot 234 and allows separation of the first and second plates. FIG. 16 shows release member 216 as a quarter-turn screw having a head 235 and a threaded portion 237 (hidden). Threaded portion 237 passes through elongated slot 234 and engages a threaded bore 236 (hidden) in first joining portion 230, and head 235 engages the upper surface 224 of second joining portion 232 to lock the first and second plates 212, 214 together. According to either configuration of release member 216, cam or quarter-turn screw, the first and second plates 212, 214 may be separated by rotating release member 216 through a predetermined angle preferably of less than 360 degrees, such as, for example, ninety degrees, to free release member 216 from

elongated slot 234 and allow the first and second plates 212, 214 to separate. One of ordinary skill in the art will know and appreciate that any number of cam or quarter-turn screw configurations may be used to releasably lock the first and second plates 212, 214 together.

Referring to FIGS. 14-16, first and second joining portions 230, 232 may each have a series of transverse ratchet teeth 262, 264 defined thereon that cooperate to lock first and second plates 212, 214 together. The position of second joining portion 232 may be varied incrementally with respect to first joining portion 232, provided that release member 216 is maintained within the boundaries of elongated slot 234, which position may be locked by the cooperation of transverse ratchet teeth 262, 264, which are pressed together by release member 216. Thus, first and second plates 212, 214 can be locked together at varying distances apart from one another, allowing sternum fixation device 210 to be used with sternums of different sizes.

FIG. 18 shows a variation of sternum fixation device 210 where release member 216 is a U-shaped pin that is received in sets of substantially aligned longitudinal bores 234 (hidden), 236 and 238 (hidden), 240 disposed in inter-digitated first and second joining portions 230, 232, as described above with respect to sternum fixation device 10. One of ordinary skill in the art will appreciate that all the configurations of the release member 16 and the first and second joining portions 30, 32, as described above with respect to sternum fixation device 10, may also be used with sternum fixation device 210.

Referring back to FIG. 15, first attachment member 222 is shown as a pair of laterally spaced-apart, generally curved hooks for engaging the intercostal spaces of a patient's sternum. First attachment member 222 may have C-shaped, J-shaped, L-shaped, or any other shaped hooks known in the art to be suitable for engaging the intercostal spaces of a sternum. One of ordinary skill in the art will appreciate that first attachment member 222 may have any number of hooks configured for engaging any respective number of intercostal spaces. In addition, first attachment member 222 can be made having various different dimensions, such as the size of the hooks and the lateral spacing therebetween, to accommodate sternums having different sizes and proportions. FIG. 16 shows a variation of first attachment member 222 where the number of hooks 270 and the lateral distance between them is adjustable. First plate 212 has a longitudinal array of mounting apertures 272 defined therein for receiving mounting bolts 274 that secure the hooks to the first plate 212, thus allowing the mounting position of the hooks to be adapted to conform to varying distances between intercostal spaces. Mounting bolts 274 are preferably recessed into

mounting apertures 272, for example, by countersinking or counterboring the apertures 272, to reduce the amount of material protruding above upper surface 218. Referring to FIGS. 17 and 18, the first attachment member 222 can have pointed, self-dissecting tip portions 276 that aid in inserting the hooks through soft tissue and muscle that is found in the intercostal spaces. First attachment member 222 can additionally have apertures 278 (shown in FIG. 17) defined therein for receiving pins that may be used to stabilize attachment member 222 in the intercostal space.

While it is apparent that the illustrative embodiments of the invention herein disclosed fulfil the objectives stated above, it will be appreciated that numerous modifications and other embodiments may be devised by those skilled in the art. For example, as shown in FIG. 17, sternum fixation device 210 may further include third attachment member 280, a threaded hole for receiving a threaded head portion 244 of a bone fastener or screw 242, and fourth attachment member 282, an intercostal space hook. One of ordinary skill in the art will appreciate that sternum fixation device 210 may include any number and combination of attachment members, such as hooks and bone screws, and release members, such as pins, U-shaped pins, and cam members. Therefore, it will be understood that the appended claims are intended to cover all such modifications and embodiments which come within the spirit and scope of the present invention.

THE CLAIMS

What is claimed is:

1. A sternum fixation device for securing parts of a sternum comprising:

a first plate having an upper surface and a sternum-contacting surface, and at least one hole passing through the upper and sternum-contacting surfaces for receiving a fastener head, the first plate further including a first longitudinal bore defining an axis oriented substantially transversely to the at least one hole;

a second plate having an upper surface and a sternum-contacting surface, and an attachment member for fixation to the sternum, the second plate further including a second longitudinal bore; and

a release member for holding the first and second plates together, wherein the first and second plates are dimensioned to mate with one another such that the first and second longitudinal bores are aligned to receive the release member, and removal of the release member from the first and second longitudinal bores allows separation of the parts of the sternum.

2. The sternum fixation device of claim 1, wherein the at least one hole is threaded to receive a threaded fastener head.

3. The sternum fixation device of claim 2, further comprising a bone fastener having a threaded fastener head and a shaft and defining a longitudinal axis that extends away from the upper surface toward the sternum-contacting surface, wherein the at least one hole is angled such that when the threaded fastener head is received in the hole, the longitudinal axis is angled toward the second plate.

4. The sternum fixation device of claim 1, wherein the attachment member is a through hole passing through the second plate upper and sternum-contacting surfaces.

5. The sternum fixation device of claim 4, wherein the through hole is threaded to receive a threaded fastener head.

6. The sternum fixation device of claim 1, wherein the attachment member is a hook member for engaging an intercostal space portion of the sternum.

7. The sternum fixation device of claim 1, wherein the attachment member comprises at least two hook members spaced apart by a distance, wherein the distance between the hook members is adjustable.

8. The sternum fixation device of claim 1, wherein the first and second plates mate with one another such that they cannot rotate with respect to one another about the release member.

9. The sternum fixation device of claim 1, wherein the release member is a pin having a tip portion with a plurality of splayed apart fingers.

10. The sternum fixation device of claim 1, wherein the release member is a taper pin.

11. The sternum fixation device of claim 1, wherein the release member is a pin defining at least one longitudinal axis and a cross-section substantially transverse to the at least one longitudinal axis, and the cross-section is ovular, circular, polygonal, rectangular, square, or triangular.

12. The sternum fixation device of claim 1, wherein:

the release member is a pin;

the first plate further includes at least one additional first longitudinal bore having an axis substantially parallel to the first longitudinal bore axis; and

the second plate further includes at least one additional second longitudinal bore;

wherein when the first and second plates are mated with one another, at least one of the first longitudinal bores is aligned with at least one of the second longitudinal bores to receive the pin.

13. The sternum fixation device of claim 12, wherein the release member is a pin having first and second spaced apart legs, and when the first and second plates are mated with one another, one of the first and second longitudinal bores are aligned to receive the first leg and another one of the first and second longitudinal bores are aligned to receive the second leg.

14. The sternum fixation device of claim 1, wherein the release member is a pin that is substantially U-shaped or T-shaped.

15. The sternum fixation device of claim 1, wherein the first and second plates mate at a mating line, and at least one of the first and second longitudinal bores is disposed at an angle with respect to the mating line.

16. A sternum fixation device for securing parts of a sternum comprising:

a first plate having an upper surface and a sternum-contacting surface, and at least one hole passing through the upper and sternum-contacting surfaces for receiving a fastener;

a second plate having at least one hook member for fixation to the sternum; and

a release member for holding the first and second plates together, wherein the release member is movably associated with at least one of the first and second plates such that it may be moved to allow separation of the two parts of the sternum.

17. The sternum fixation device of claim 16, wherein the first plate further includes at least one first longitudinal bore defining an axis oriented substantially transversely to the at least one through hole, and the second plate further includes at least one second longitudinal bore, and the first and second plates are dimensioned to mate with one another such that the at least one of first and second longitudinal bores are aligned to receive the release member such that removal of the release member from the first and second longitudinal bores allows separation of the two parts of the sternum.

18. The sternum fixation device of claim 16, wherein the release member comprises a quick-release fastener and a predetermined rotation of the quick-release fastener allows separation of the two parts of the sternum.

19. The sternum fixation device of claim 16, wherein the release member comprises a cam located on one of the first and second plates that is movable between a locking and a releasing position, and wherein the other plate further includes an aperture for receiving at least a portion of the cam such that when the cam is in the locking position the first and second plates are held together, and when the cam is in the releasing position the first and second plates are allowed to separate.

20. The sternum fixation device of claim 16, further comprising a set of mating ratchet teeth disposed on each of the first and second plates capable of fixing the first and plates together at a predetermined distance from one another.

21. The sternum fixation device of claim 16, wherein the second plate further comprises at least two hook members for fixation to the sternum, wherein a distance between the hook members is adjustable.

22. The sternum fixation device of claim 16, wherein the first plate further comprises at least one hook member for fixation to the sternum.

23. A sternum fixation device for securing parts of a sternum comprising:

a first plate having an upper surface and a sternum-contacting surface, and at least one threaded hole passing through the upper and sternum-contacting surfaces for receiving a threaded fastener head;

a second plate having at least one attachment member for fixation to the sternum; and

a release member for holding the first and second plates together, wherein the release member is movably associated with at least one of the first and second plates such that it may be moved to allow separation of the two parts of the sternum.

24. The sternum fixation device of claim 19, wherein the release member comprises at least one quick-release fastener and a predetermined rotation of the at least one quick-release fastener allows separation of the two parts of the sternum.

25. The sternum fixation device of claim 19, wherein the second plate has an upper surface and a sternum-contacting surface, and the attachment member is a threaded hole passing through the second plate upper and sternum-contacting surfaces for receiving a threaded fastener head.

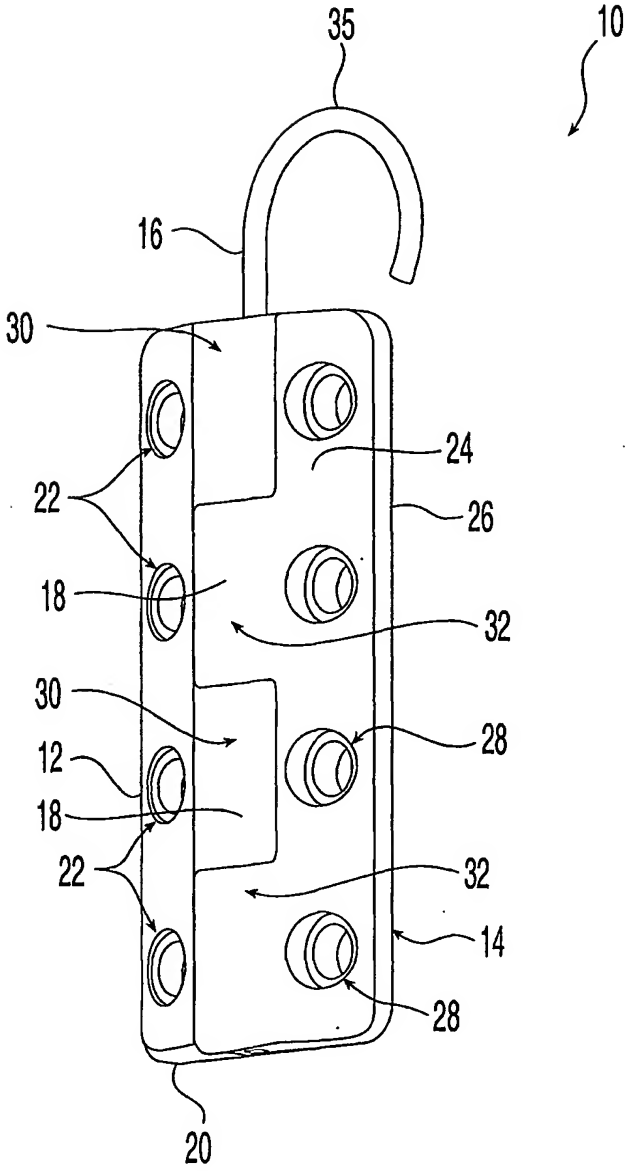


Fig. 1

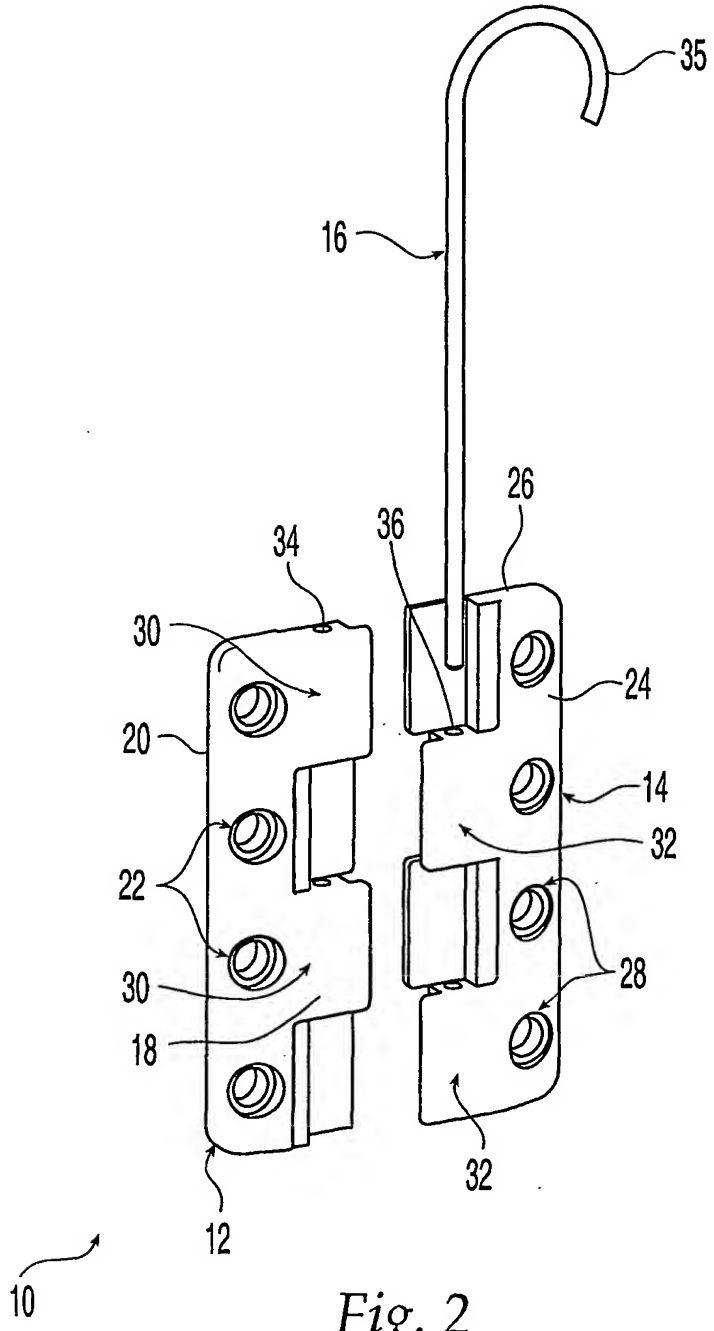


Fig. 2

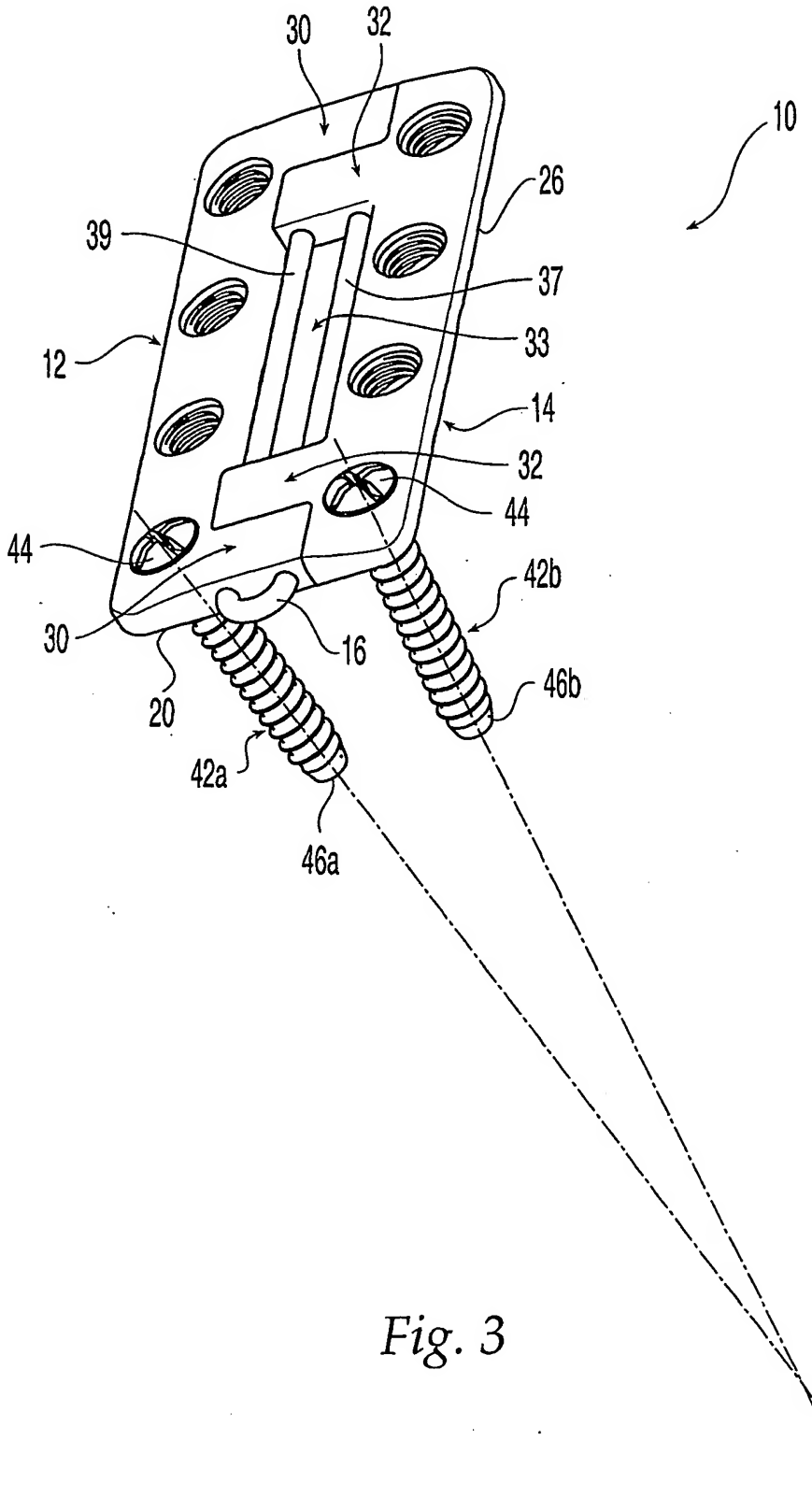


Fig. 3

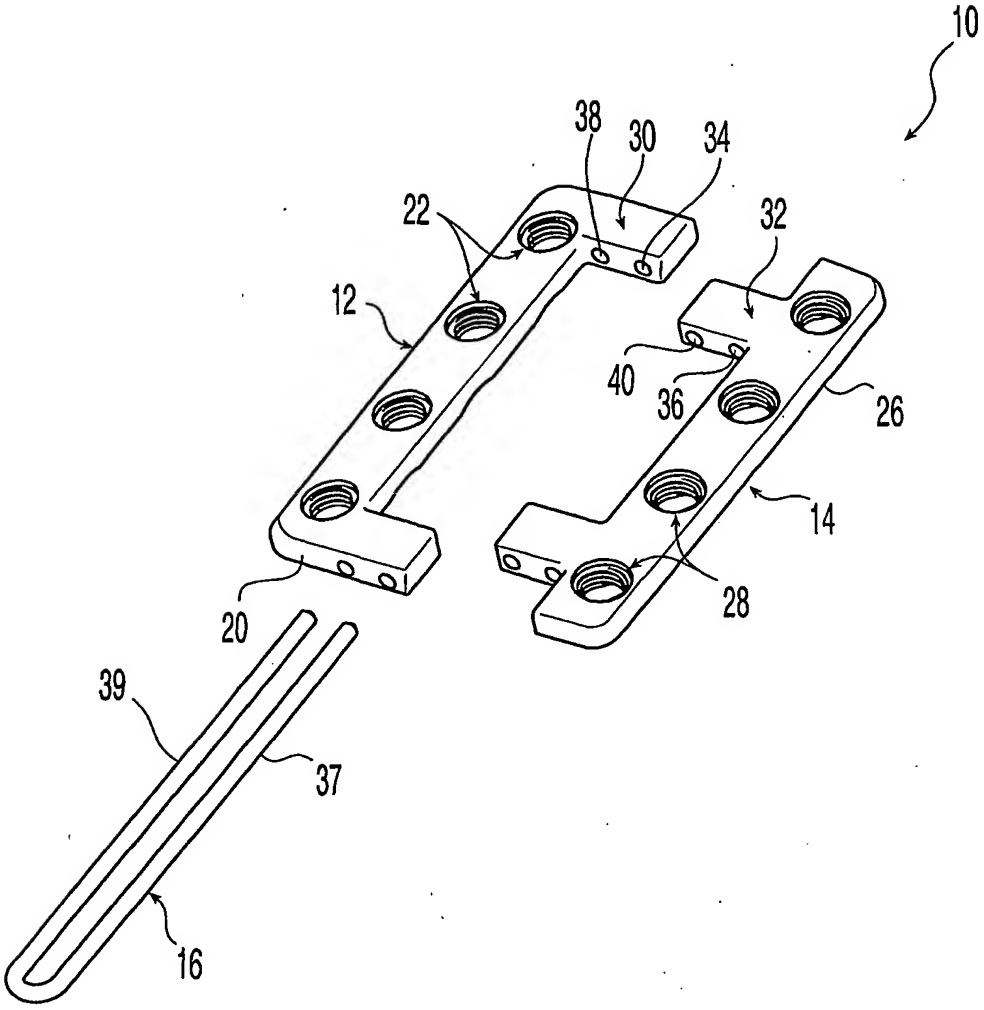


Fig. 4

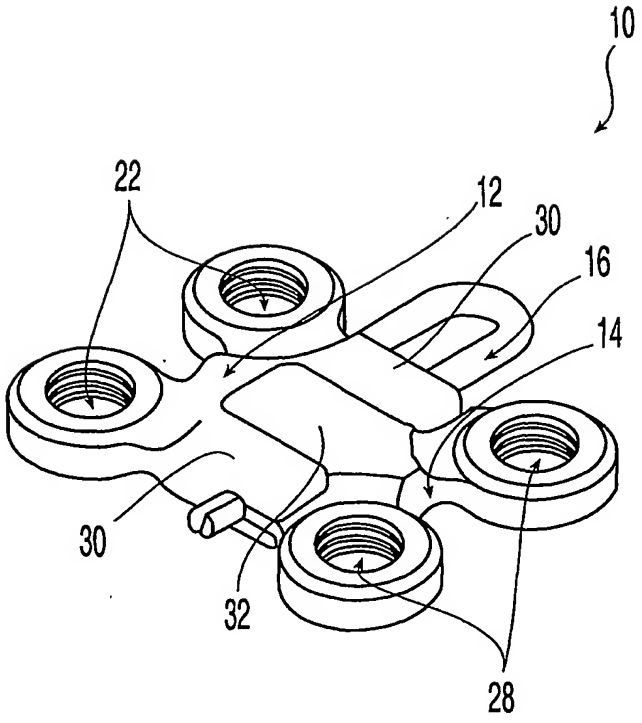


Fig. 5

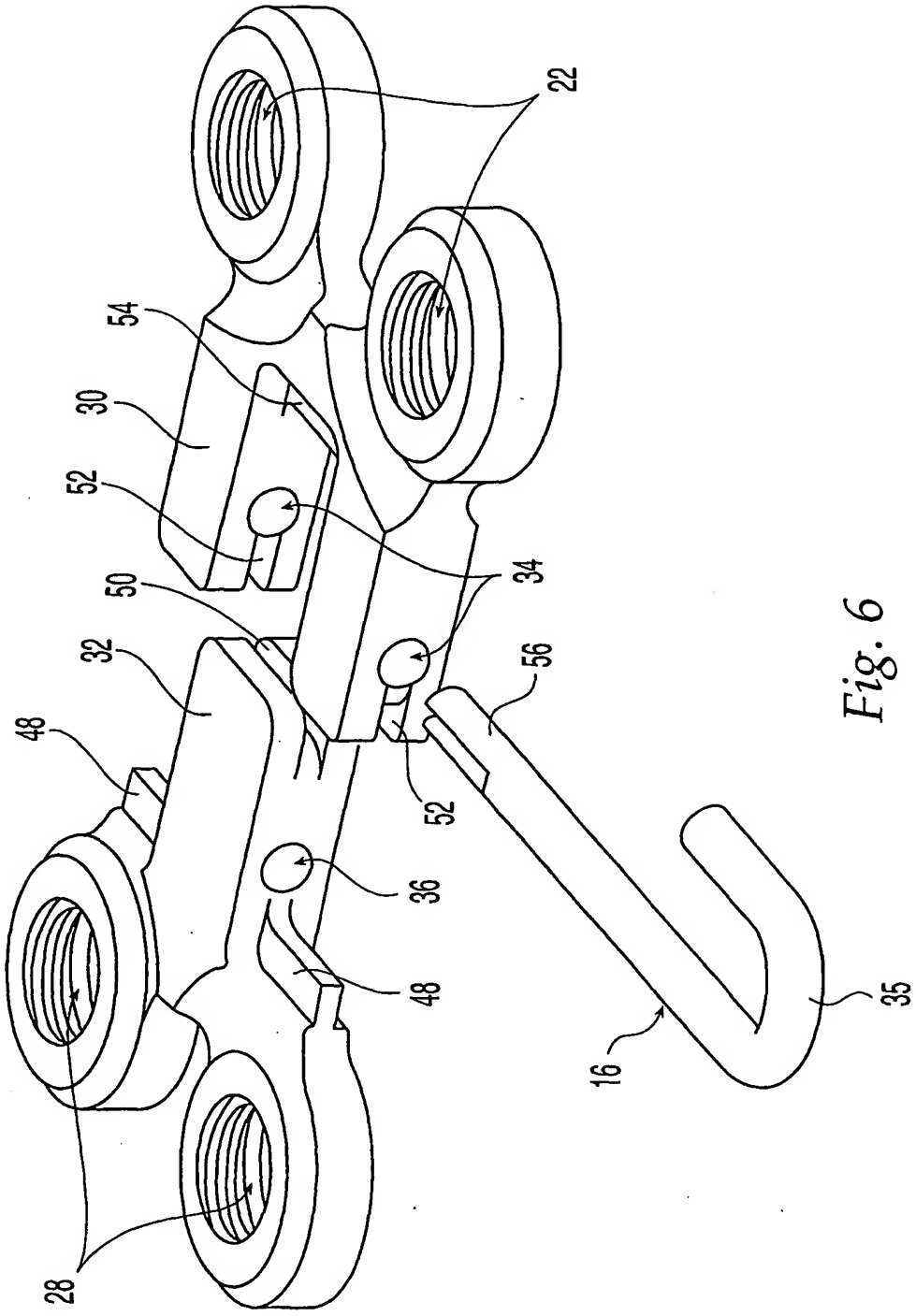


Fig. 6

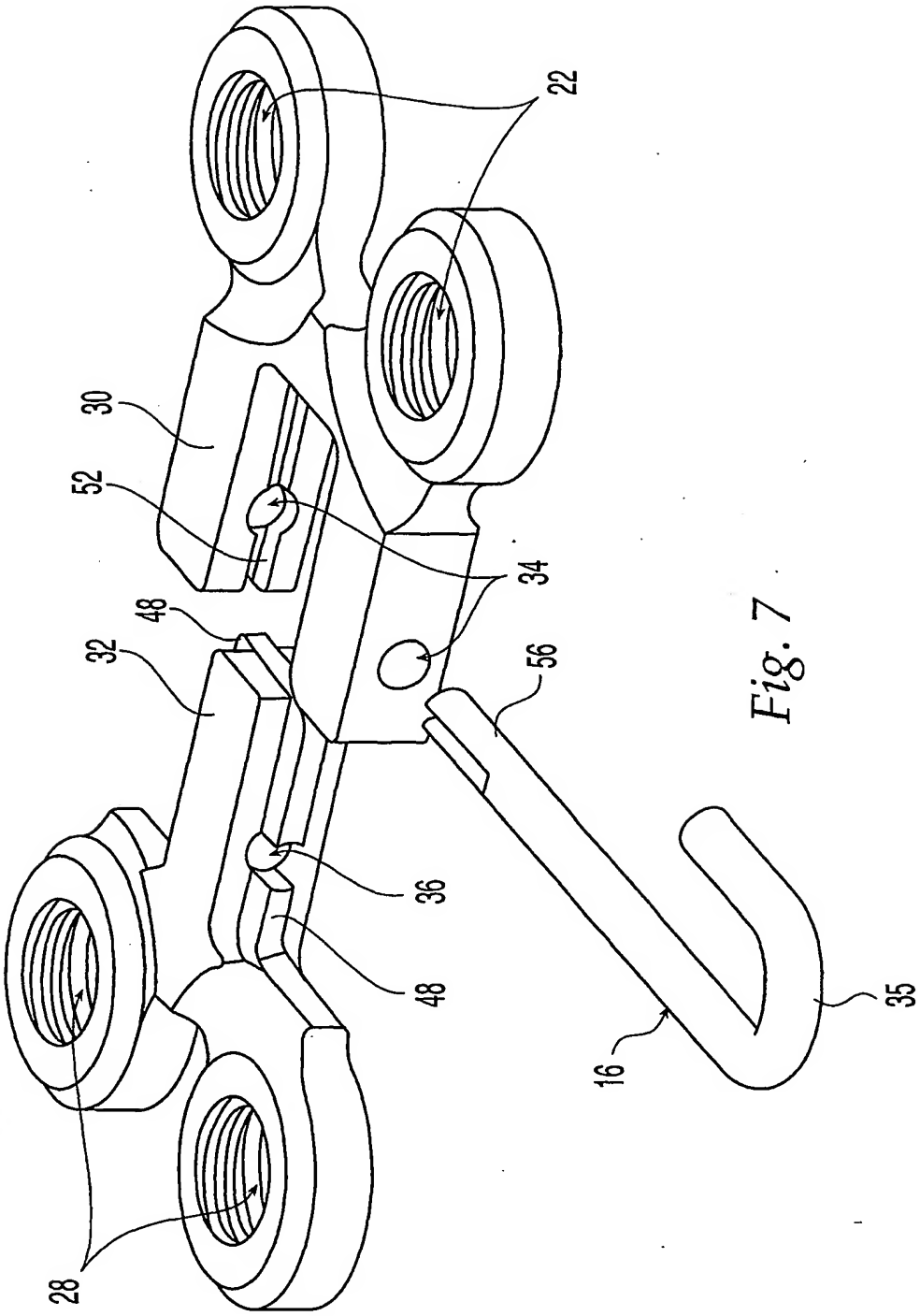


Fig. 7

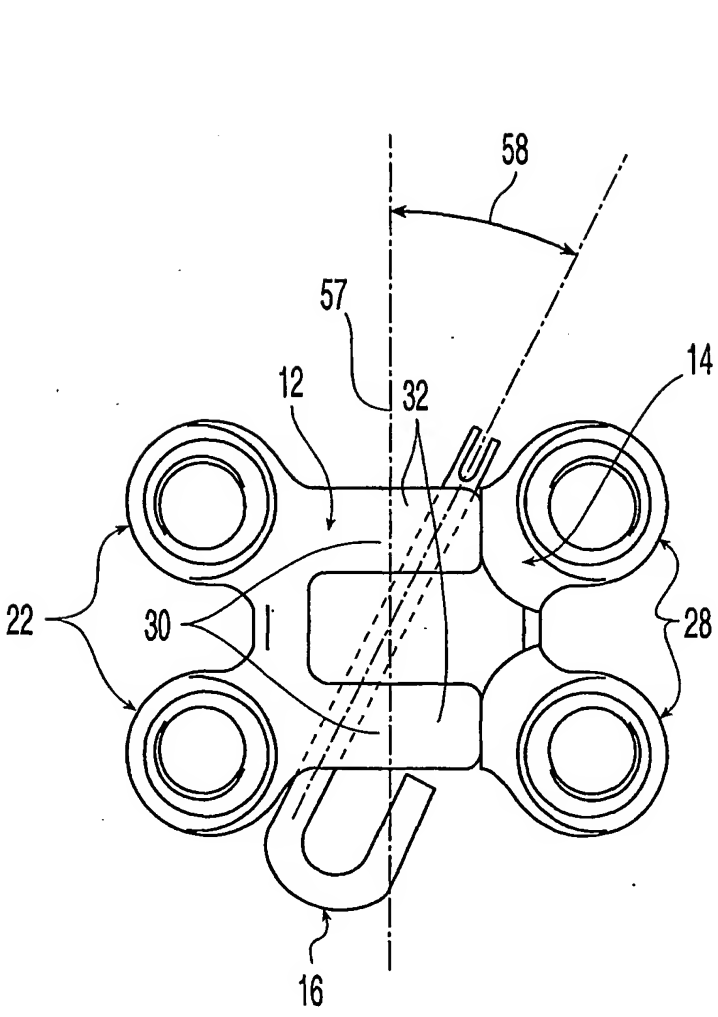


Fig. 8

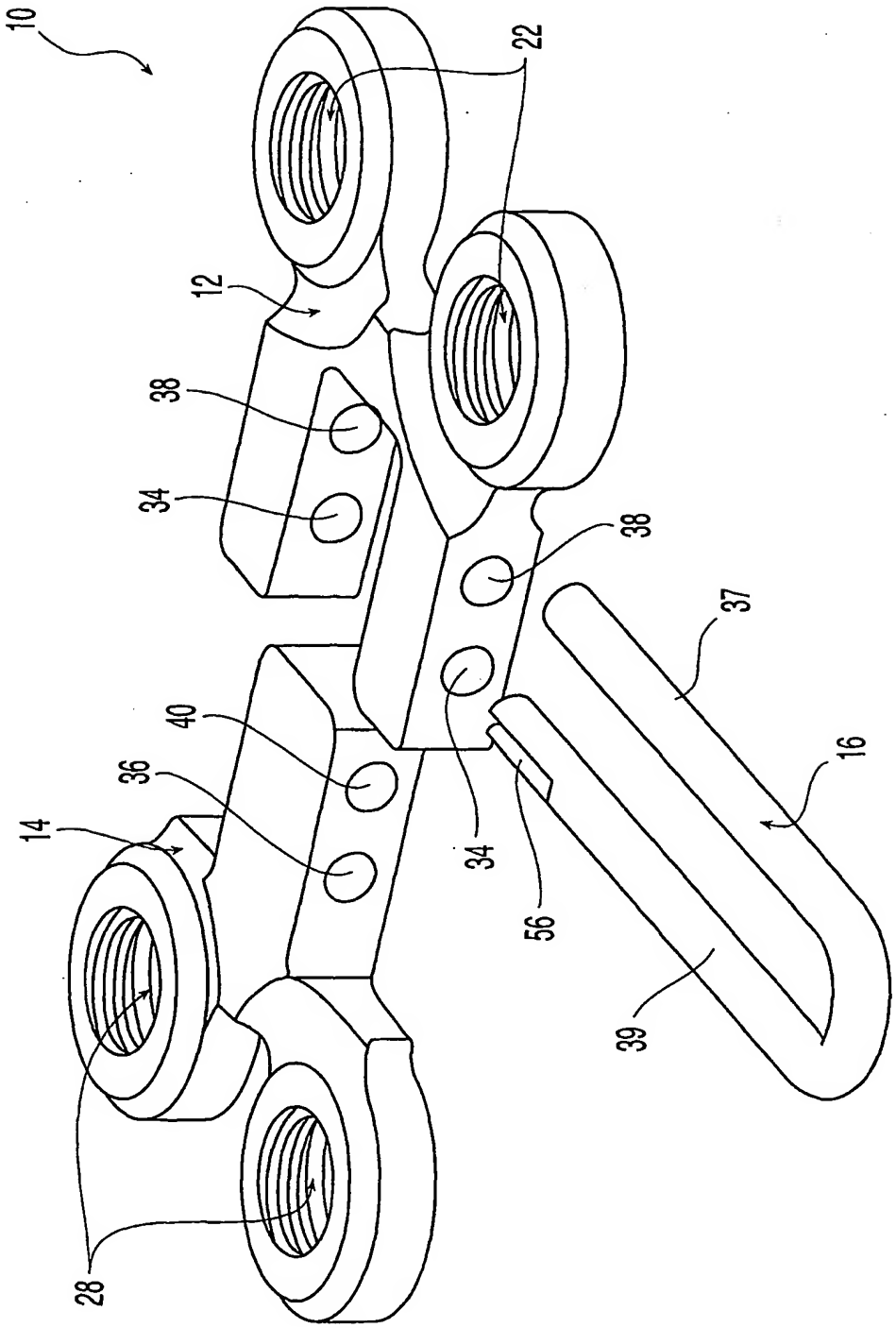


Fig. 9

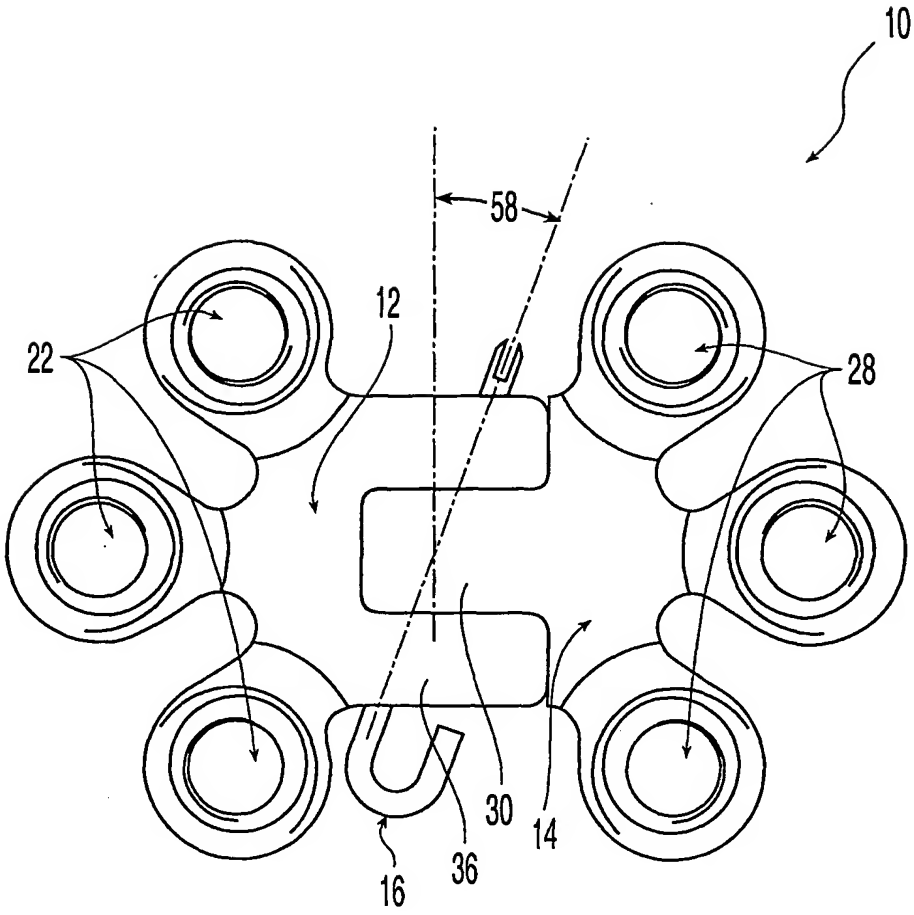


Fig. 10

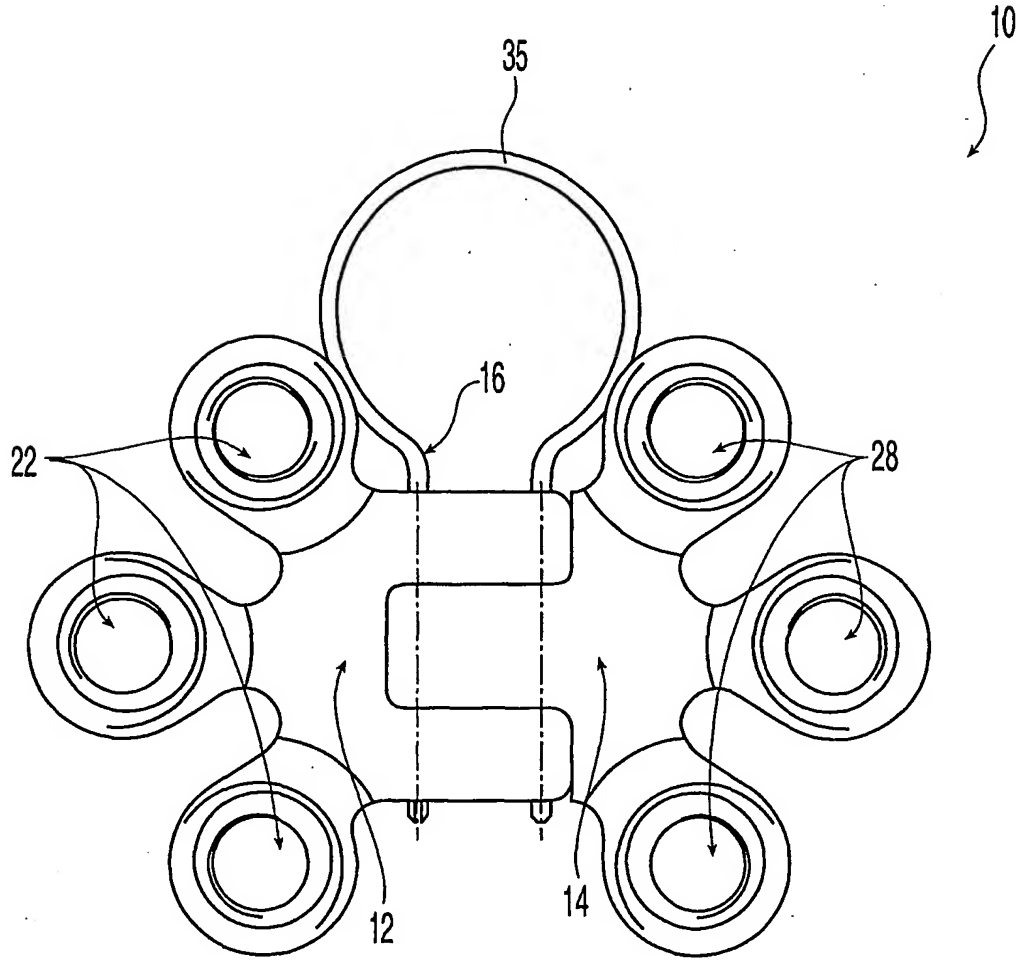


Fig. 11

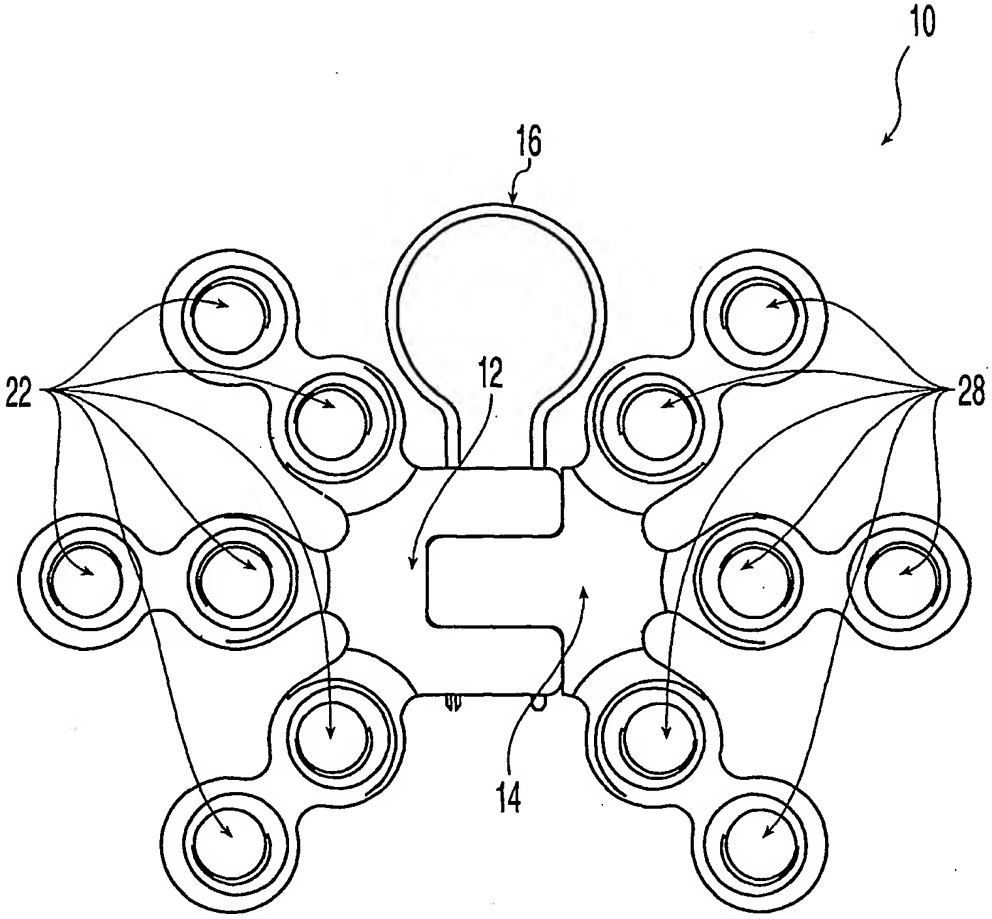


Fig. 12

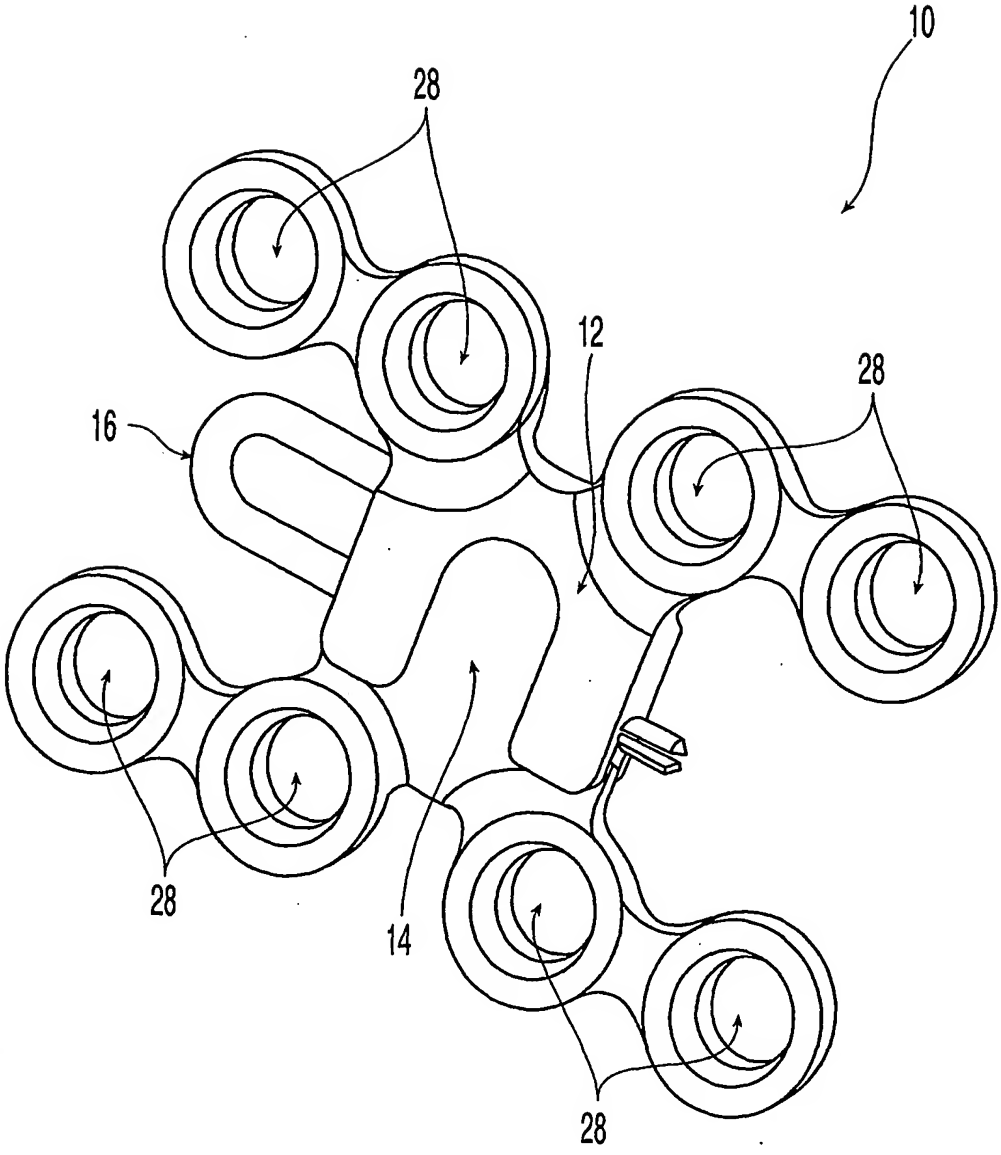


Fig. 13

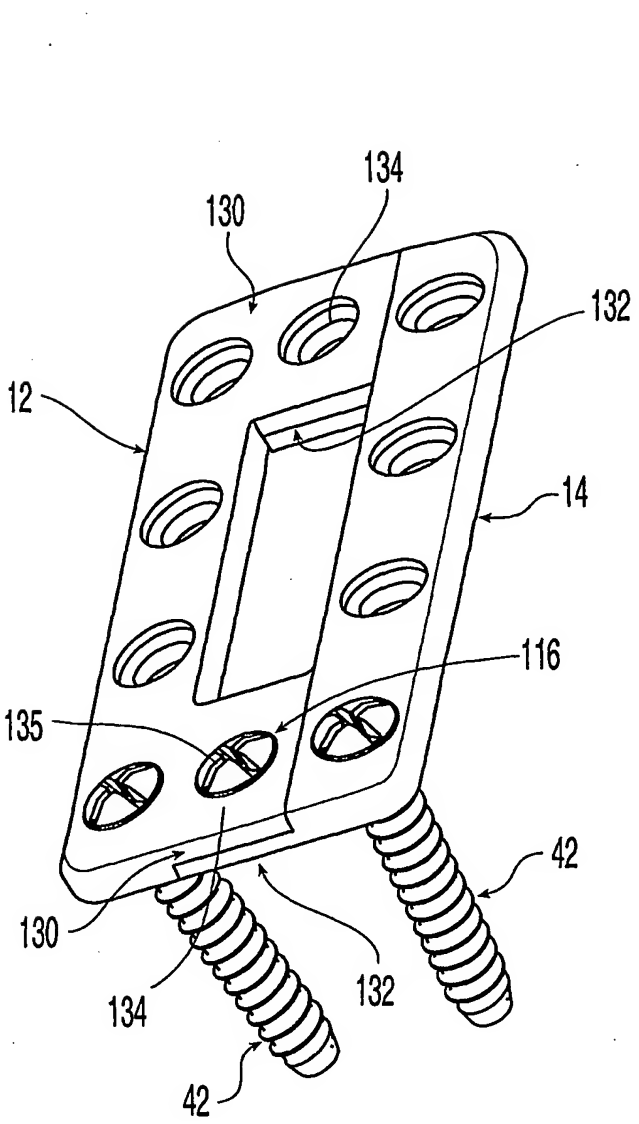


Fig. 14

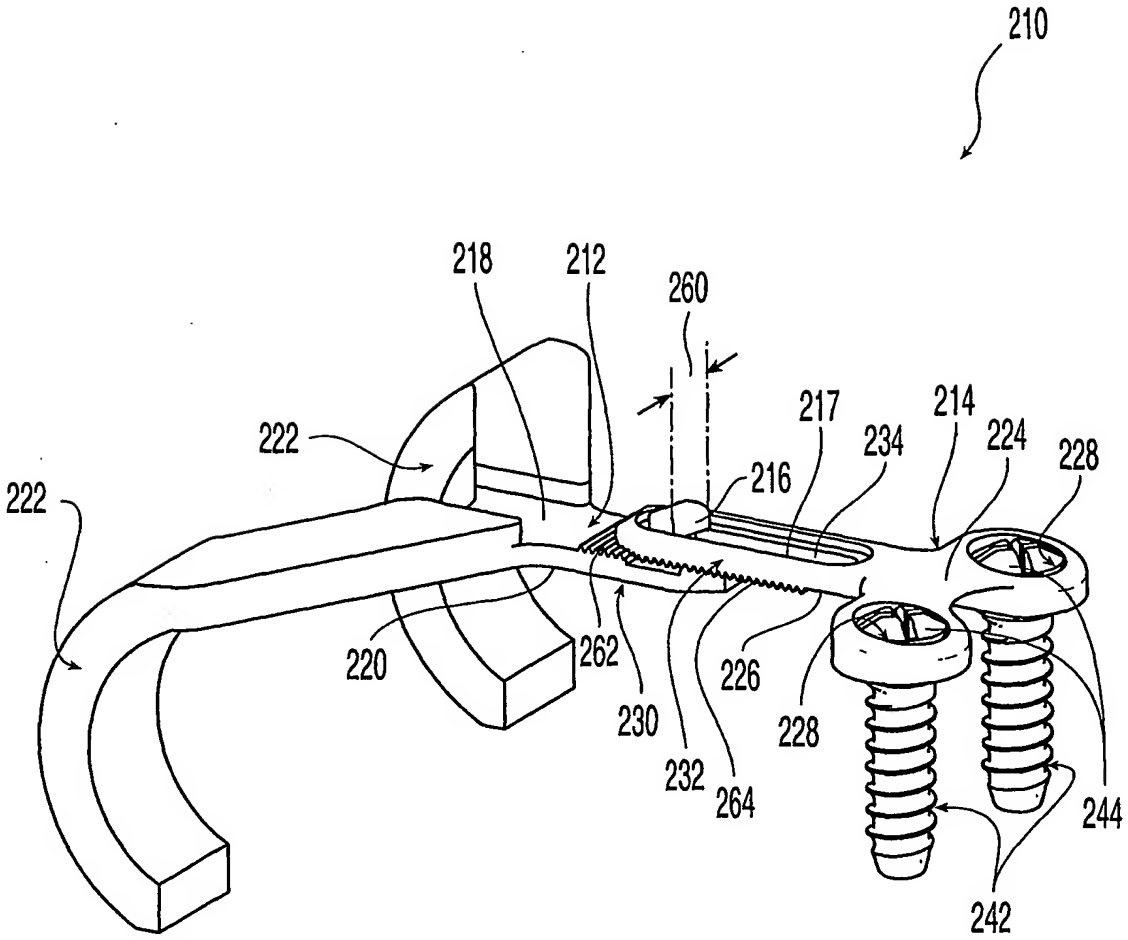

210
218
212
260
222
217
214
234
224
228
222
216
220
262
230
226
228
232
264
244
242

Fig. 15

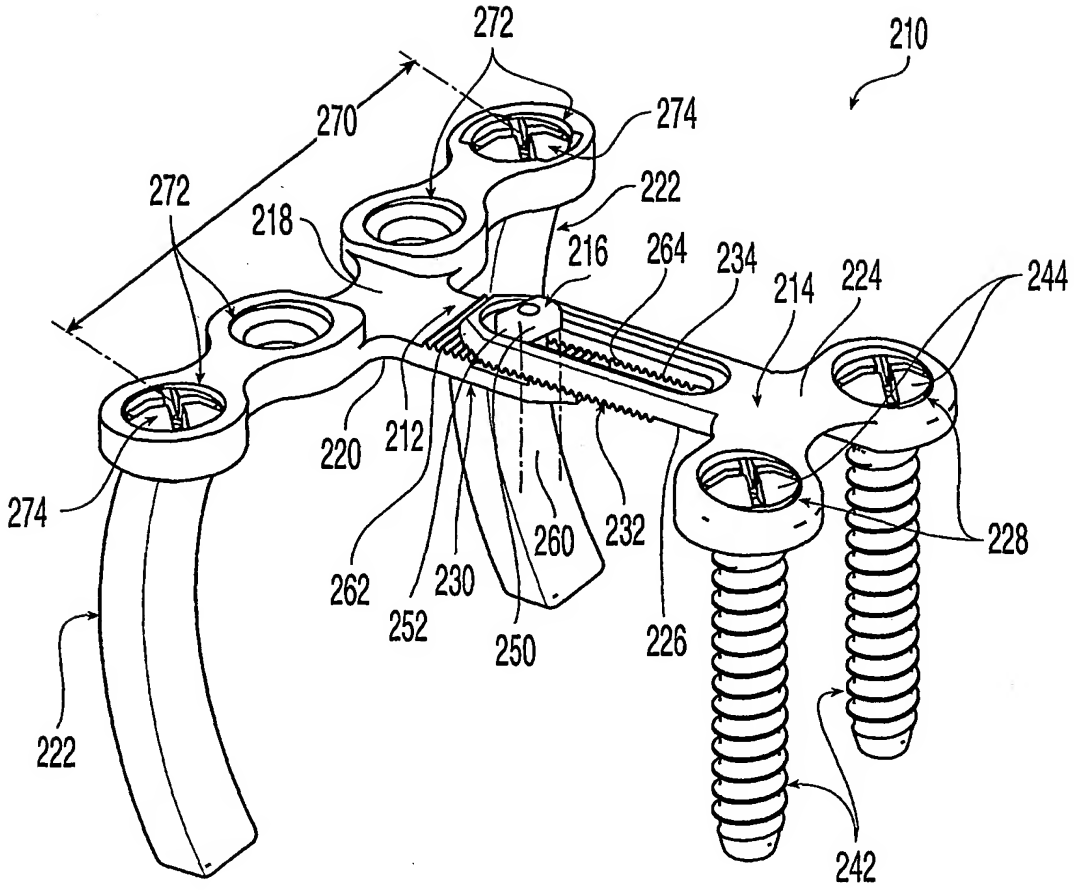

272
210
270
274
272
222
218
216
264
234
214
224
244
220
212
274
260
232
228
262
230
252
250
226
222
242

Fig. 16

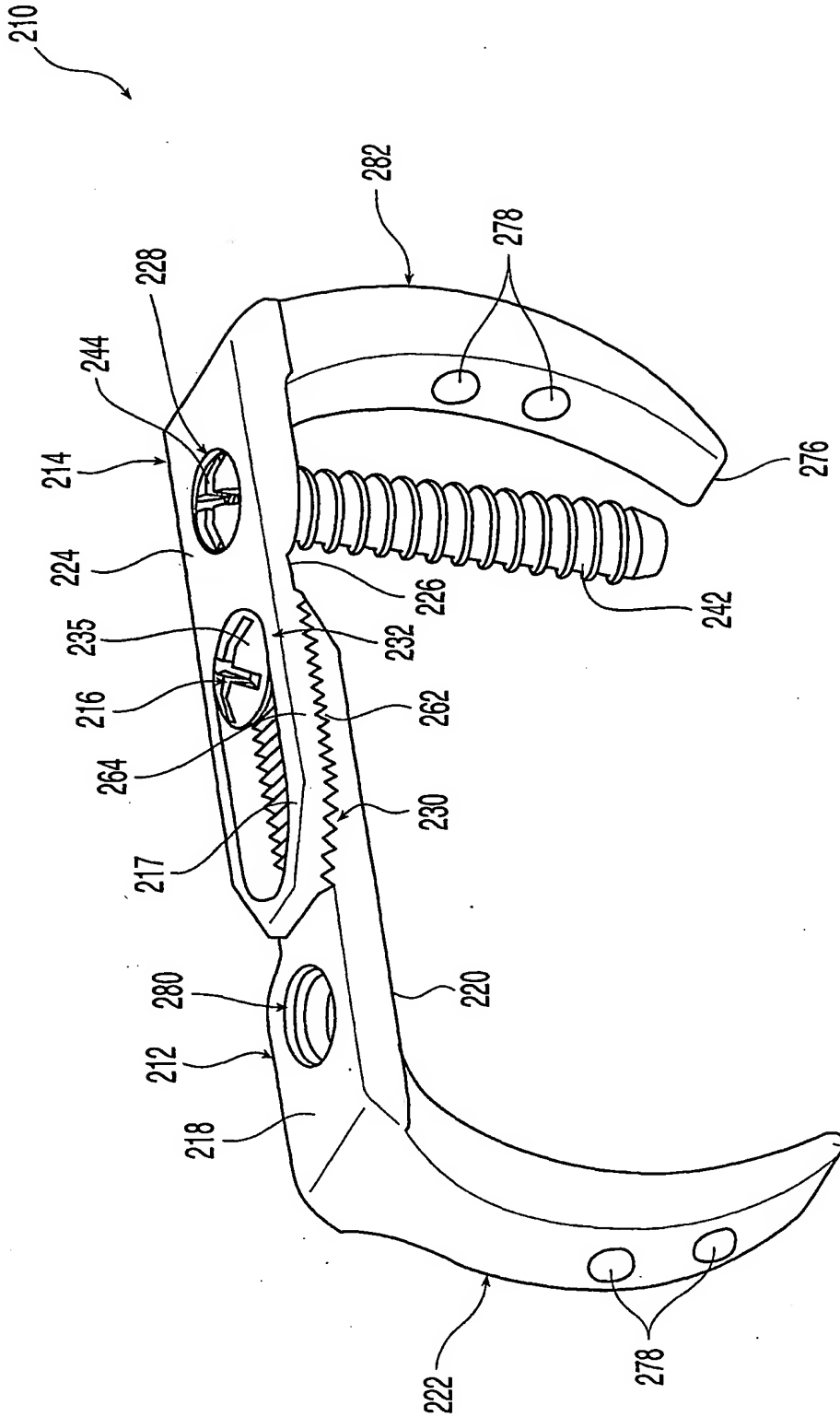

210
282
278
228
244
214
276
224
226
242
235
232
216
262
264
230
217
280
220
212
218
276
222
278

Fig. 17

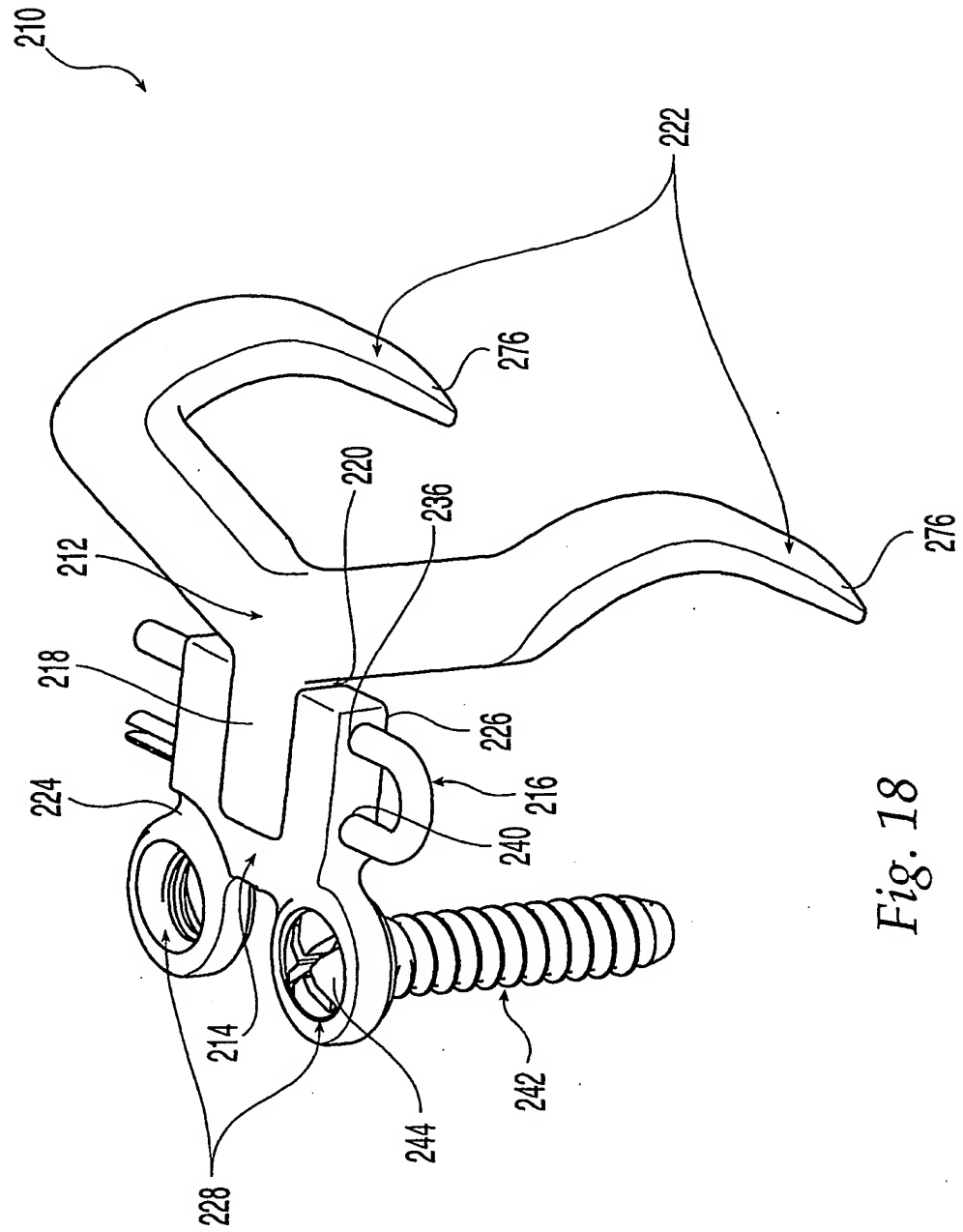


Fig. 18

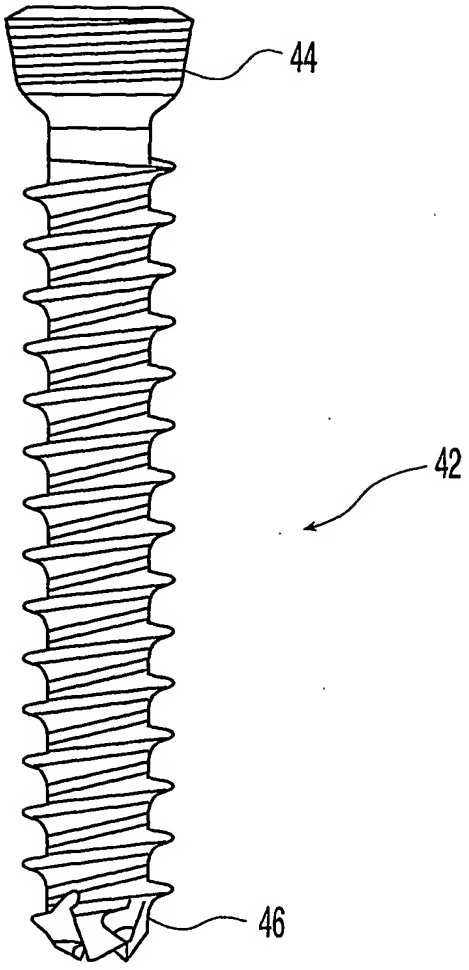


Fig. 19

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 02/05310

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B17/80

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B E05D

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	PATENT ABSTRACTS OF JAPAN vol. 2000, no. 19, 5 June 2001 (2001-06-05) & JP 2001 037767 A (KYOWA TOKEI KOGYO KK), 13 February 2001 (2001-02-13) abstract figures 2,3	1,4,11
X	DE 121 383 C (F. W. BERTRAM) 28 June 1901 (1901-06-28) figures 1,2	1,4,11
A	US 6 051 007 A (CHAPMAN TROY ET AL) 18 April 2000 (2000-04-18) abstract; claims 1,12,21; figures 1,8,10-13A	1,8, 11-14, 16-18, 20,22-24

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
2 July 2002	09/07/2002

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax (+31-70) 340-3016	Macaire, S

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 02/05310

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
A	US 3 068 869 A (LUTES HAROLD R ET AL) 18 December 1962 (1962-12-18) claim 1; figures 1-6	1,16,23
A	US 6 053 915 A (BRUCHMANN GUILLERMO VICTORIO) 25 April 2000 (2000-04-25) abstract; figure 1	1,16
A	DE 93 21 544 U (KOENIGSEE IMPLANTATE UND INSTR) 23 September 1999 (1999-09-23) abstract; figures 1,2	2,4,5

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US 02/05310

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
JP 2001037767 A	13-02-2001	US 6355036 B1	12-03-2002
DE 121383 C		NONE	
US 6051007 A	18-04-2000	NONE	
US 3068869 A	18-12-1962	NONE	
US 6053915 A	25-04-2000	NONE	
DE 9321544 U	23-09-1999	DE 4341980 A1 DE 9321544 U1	14-06-1995 23-09-1999